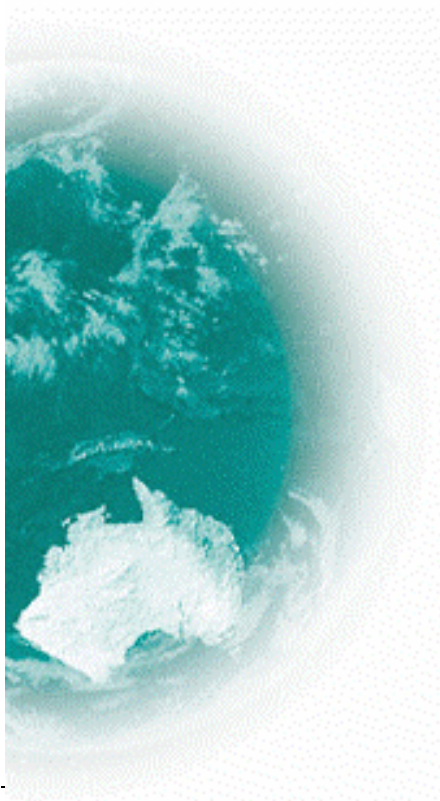




**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

# **A Proposal for the Re-classification of Joint Replacement Implants**

*Consultation Paper*



**October 2009**

# Consultation Paper: A Proposal for the Re-classification of Joint Replacement Implants

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## ***Introduction***

Joint replacement is a commonly performed surgical procedure and, in most instances, is highly successful in alleviating pain and disability. The rate of such surgery has increased rapidly over recent years, and this increase is expected to continue with approximately 70,000 procedures anticipated in 2009.

The success of joint replacement surgery can depend on many factors, some related to the device itself, some patient related, others reliant on patient/prosthesis matching and others on surgical technique.

With the rapid rate of expansion of technologies, materials, construction techniques used in the manufacturing process and implantation techniques, there needs to be assurance that regulatory review processes are adequate to ensure long term device performance when a new product is introduced. This is becoming more important particularly as joint replacements are now being used in younger and more active populations.

The internationally harmonised Global Harmonization Task Force (GHTF) regulatory framework, upon which Australia's device regulatory framework is based, recognises the need to balance appropriate levels of pre and post-market monitoring of device safety with the need to allow timely access to innovative technology aimed at improving patient outcomes.

Historically, it has been difficult for a manufacturer to accurately determine device performance and longevity without the use of lengthy clinical trials. Such trials are difficult to conduct by virtue of the nature of the device and the time necessary to accumulate meaningful data, and so manufacturers and clinicians have made use of post-market monitoring tools such as device registries to gather information on short and long term performance.

As a consequence, it is possible some devices are marketed prior to compilation of evidence to support long term performance and may subsequently be withdrawn when post-market evidence suggests higher revision rates than the general population of equivalent devices.

The National Joint Replacement Register (NJRR), established in 1999 by the Australian Orthopaedic Association with funding from the Australian Government, began collecting data with the aim of improving patient outcomes for those receiving total or partial joint replacements. It determines outcomes by collection of uniform data defining patient characteristics, prostheses type and features, method of fixation and surgical technique used. Although data collection began in 1999, it is only in recent years that sufficient data has become available to provide a measure of prostheses' performance. Recent data has shown that there appears to be a higher than average revision (failure) rate for some orthopaedic joint replacement implants than others, which is a cause for concern.

Additionally, there has been a recent classification change in Europe (from Class IIb to III) for joint implants. There are also differences in the pre-market requirements for joint implants supplied in Australia when compared with other international regulators such as the USA, Canada and Japan. Hence, Australia's regulatory approach to these products is currently out of step with international counterparts. There are risks for Australia in this position, with the potential for implants unacceptable to other regulators being legally available in Australia.

For these reasons the Therapeutic Goods Administration (TGA) proposes re-classifying joint replacement implants to require a higher level of regulatory oversight (from Class IIb to Class III). The regulatory requirements and consequences of making this change are discussed in the paper. The purpose of this proposal is to provide for an increased level of pre-market regulation for these implants while also enhancing TGA's post-market controls over this important group of medical devices. The TGA welcomes comments on this proposal.

## Scope

**Joint Replacement Implants** are taken to be implantable artificial substitutes for one of the major natural load bearing orthopaedic joints in the human body; that is, the hip, the knee or the shoulder.

These joint replacement implants may either be supplied as a complete replacement for the articulated joint, in which case they are commonly referred to as **Total Joint Replacement Implants**; as separate component parts, which are indicated to be used as part of a specified Total Joint Replacement; or, component parts intended for partial replacement of the articulating surfaces.

This paper is **not** intended to consider the classification of devices such as bone cements, fixation screws, wedges, cement restrictors, etc, used in an ancillary manner to supplement or assist the function of the joint replacement implant.

## Key Definitions

The *Therapeutic Goods Act 1989* and subordinate regulations do not currently define total joint replacement implants. The following definitions are taken, in part, from the Global Medical Device Nomenclature (GMDN) System<sup>1</sup>:

**Hip, prosthesis, internal, total** - An implantable artificial substitute for the hip joint usually consisting of femoral and acetabular matching components. Additional devices, for example, screws, cables and bolts, may be included in accordance with the design of the total replacement.

**Hip, prosthesis, internal, partial** - An implantable artificial substitute for part or all of either of the articulating surfaces of the natural hip joint, or for interposing between the articulating surfaces of the joint.

**Knee, prosthesis, internal, total** - An implantable artificial substitute for a total knee replacement that replaces all of the articulating surfaces of the damaged/degenerative knee joint. This device may be constrained, semi-constrained or unconstrained. It may be linked as in a hinge or consist of separate parts designed to articulate together.

**Knee, prosthesis, internal, partial** - An implantable artificial substitute for part or all of either of the articulating surfaces of the natural knee joint, or for interposing between the articulating surfaces of the joint.

**Shoulder, prosthesis, internal, total** - An implantable device used to replace or repair the articulating surfaces of the shoulder. It may be constrained, semi-constrained or non-constrained.

**Shoulder, prosthesis, internal, partial** - An implantable artificial substitute for part or all of either of the articulating surfaces of the natural shoulder joint, or for interposing between the articulating surfaces of the joint.

All of these devices may be constructed of metal, ceramic, carbon, polymer or a combination of these. The implants may be designed to be used with or without bone cement.

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<sup>1</sup> The Global Medical Device Nomenclature Code (GMDN) is a unique identification number for a particular type of device. For example GMDN 36316 describes a total hip prosthesis, including all femoral and acetabular components

## ***The Proposal***

The TGA considers that the most appropriate mechanism to address the identified issues and to ensure public health and safety is maintained and improved with regard to major joint replacement implants, is to amend the Regulations by re-classifying total and partial hip, knee and shoulder implants from Class IIb to Class III medical devices.

Implementation of this proposal would require individual models of total or partial hip, knee and shoulder implants to undergo an increased level of pre-market review prior to marketing authorisation being given and the device entered on the Australian Register of Therapeutic Goods (ARTG). It will also facilitate post-market monitoring activities undertaken by the TGA.

## **Issues to be Considered**

The TGA believes there are a number of issues associated with the current level of regulation of orthopaedic implants that require consideration:

- the long-term performance reports, which suggest the need for increased pre-market review;
- the need for an enhanced capacity to monitor post-market performance of these devices;
- the benefits in aligning Australian requirements with international standards, especially as approximately 90 per cent of devices used in Australia are imported;
- the importance of balancing timely access to innovative therapies with appropriate regulatory oversight;
- the costs of regulation and the potential for this to result in a reduction in the numbers of joint implants available on the market; and
- potential risks associated with joint implants that are unacceptable in Europe being supplied in Australia as a result of the classification change in Europe to from Class IIb to Class III.

## **Proposed Transition Timeframes**

The proposal to reclassify joint replacement implants has direct implications for products currently included as Class IIb devices on the ARTG under a single entry for a 'kind of medical device' and consideration is needed in transitioning these products to Class III medical devices.

The proposed transition period is two years and the process to achieve this is outlined below.

Prior to commencement of the transition period, sponsors will be required to notify the TGA of each family name/model number considered included in their ARTG entries.

At the time of introduction of the amended Regulations, all implants subject to this proposal and included in the ARTG under an entry for a Class IIb 'kind of medical device' will continue to be included on the ARTG for the duration of the transition period, which is proposed to be a maximum of 2 years.

Sponsors of products included on the ARTG at the date of commencement of the amended Regulations will be required to submit new applications for these products within two years. These devices will undergo an appropriate assessment by TGA – either an application audit or a review of the manufacturer's application of a relevant conformity assessment procedure. Supply of these products will be allowed to continue until the application is finally determined.

For applications for affected Class IIb medical devices in process at the time of the commencement of the transition period, sponsors will be given the option to ‘convert’ these to applications for Class III medical devices on payment of a supplementary application fee equivalent to the difference between a Class IIb and Class III application fee. If the application is not converted, it will be terminated, and application fees will be forfeited.

Devices that will not be transitioning to Class III medical device inclusions may continue to be supplied for two years from commencement of the amended Regulations, but cannot be supplied beyond this period.

Applications for devices covered by a current Class IIb ARTG inclusion but not notified to the TGA at the commencement of the transition, and for which a subsequent application for inclusion as Class III devices is received after commencement of the transition will be considered as new applications with the exception they can continue to be supplied for the duration of the two year transition. If review and marketing approval is not completed at the end of the transition period, supply of these devices must cease until the application is finally determined and the product entered on the ARTG.

For new products intended for introduction to the market after commencement of the transition period, sponsors will need to submit an application for a Class III medical device. These devices will be required to undergo an appropriate assessment – either an application audit or a review of the manufacturer’s application of a relevant conformity assessment procedure. As with any new application for inclusion in the ARTG these products will not be able to be supplied until such assessment has been completed and the device entered on to the ARTG.

### **Availability of Non-transitioned Implants for Revision Surgery**

It is recognised that there will be a continued need for some products which will not to be transitioned to Class III medical devices, for use in partial revision procedures.

Sponsors will be able to provide these devices using the existing arrangements for supply of devices that are not included in the ARTG for medical devices under provisions of the Special Access Scheme.<sup>2</sup> However, sponsors should note approvals will only be provided for revision procedures of existing implants, not for primary replacement of some or all of the natural joint.

### **Legislation amendments**

Legislation will require amendment in only one area – addition of a new classification rule to Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 to indicate these products are considered Class III. An explanatory note will also be required to exclude ancillary devices such as bone screws, bone cement, etc from the classification rule.

### **e-Business systems**

No amendment will be required to the e-Business environment as the ARTG record for Class III medical devices already carries the unique product identifier for the device.

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<sup>2</sup> [www.tga.gov.au/docs/html/unapp.htm](http://www.tga.gov.au/docs/html/unapp.htm)

## **Background**

The Australian regulatory framework adopts a classification system to categorise medical devices based on the risk the device presents to the patient, the user and the environment. The system uses a set of classification rules based on

- the manufacturer's intended use
- the level of risk presented by use of the device, and
- the degree of invasiveness in the human body.

The five classes of medical devices, starting with the lowest designated level of risk are:

- Low risk                                      Class I
  - Class I supplied sterile
  - Class I with a measuring function
- Low/medium risk                          Class IIa
- Moderate/higher risk                    Class IIb
- High risk                                      Class III
- High risk                                      Active Implantable Medical Devices (AIMD)

Consistent with the classification recommended by the GHTF, the Australian regulatory framework introduced in 2002 classified joint replacement implants as Class IIb medical devices.

Class IIb also includes all medical devices implanted in the body for longer than 30 days, and includes such devices as non-absorbable sutures, peripheral vascular grafts or stents, intra-ocular lenses, maxillio-facial implants, bone cements and bone screws.

Class III medical devices, which are implantable and considered to present a higher risk, include devices such as:

- devices in direct contact with the heart, the central circulatory system or the central nervous system,
- devices intended to have a biological effect,
- devices intended to be wholly or mostly absorbed by the body,
- devices intended to undergo a chemical change within the body, or
- devices intended to deliver a medicine.

The classification of a medical device has a direct impact on the level of pre-market assessment of the manufacturer's systems and procedures, and of the medical device. The pre-market assessment includes a review of the procedures used by a manufacturer to demonstrate compliance with the Essential Principles (refer to Attachment 1) outlined in Schedule 1 to the Therapeutic Goods (Medical Devices) Regulations 2002. This assessment is undertaken by a Conformity Assessment Body (CAB).

For manufacturers resident in Australia, this pre-market assessment is currently undertaken by the TGA. For manufacturers located overseas, the manufacturer may ask the TGA to undertake the assessment or, more commonly, the assessment will be undertaken by one of the Notified Bodies (NB) designated by a Competent Authority in the European Union for the purposes of the European Medical Device Directive.

### **Regulatory Documentation Requirements and Review – Class IIb**

In preparation for assessment by a CAB, a manufacturer of a Class IIb medical device is required to prepare technical documentation detailing:

- their Quality Management System (QMS),
- the design of the device to which the QMS is applied,
- the inspection and quality assurance procedures applied in the manufacture of the device,
- the implementation of a post-market monitoring system to assess device performance when introduced to the market, and
- the application of relevant conformity assessment standards.

During the assessment of the manufacturer and the device(s), the CAB is required to ensure the manufacturer has followed their documented procedures, and produced evidence and documentation to support their Declaration of Conformity<sup>3</sup> for the device, and may examine some of the documentation. If satisfied all is in order, the CAB will issue a Conformity Assessment Certificate. In Europe this certificate, known as an *EC Certificate*, is issued under the Medical Devices Directive 93/42/EEC.

In Australia, for Class IIb medical devices, on application by the sponsor, the TGA accepts the EC Certificate as sufficient evidence the manufacturer and product have undergone an appropriate level of review and an entry is created on the ARTG for the 'kind of medical device'. In such circumstances Class IIb medical devices, such as joint replacement implants, are not subject to a mandatory application audit by TGA prior to inclusion on the ARTG.

### **Regulatory Documentation Requirements and Review – Class III**

In addition to the technical documentation described above for a Class IIb device, the regulatory framework requires a manufacturer of a Class III medical device to separately prepare a design dossier relating to:

- the design of the medical device,
- the manufacturing process for the device, and
- the intended performance of the device.

The GHTF, in their published document *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*,<sup>4</sup>

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<sup>3</sup> A Declaration of Conformity is a legally binding declaration drawn up by the manufacturer, identifying the manufacturer, the device(s) and includes statements that the devices are in compliance with the applicable provisions of the Essential Principles, the device(s) are correctly classified, an appropriate Conformity Assessment procedure has been applied and an appropriate Quality Management System has been applied to the manufacture of the device(s).

<sup>4</sup> [www.GHTF.org](http://www.GHTF.org)

which is a consensus view of the content of a design dossier, suggests such a document should contain, as appropriate:

- A device description and product specification, including variants and accessories with reference to similar and previous generations of the device
- Samples of device labelling
- Design and manufacturing information
  - device design
  - manufacturing processes
  - design and manufacturing sites
  - essential principles (EP) checklist
  - risk analysis and risk control summary
  - product verification and validation
- Specific evidence supporting compliance with the essential principles
  - material biocompatibility
  - details and regulatory status of any medicinal substances present
  - evidence of biological safety of human or animal origin materials
  - sterilisation processes and validation
  - software verification and validation
  - results of animal studies
  - clinical evidence of efficacy.

Thus, in addition to auditing the manufacturer to ensure they have a functional QMS in place, the conformity assessment procedures for a Class III device require the CAB to review the design dossier and verify that the evidence presented in the dossier supports the Declaration of Conformity for the device. If satisfied, the CAB will issue a Design Examination Certificate, which is applicable only to the specific device(s) that was subject to assessment.

In the event a manufacturer makes significant changes to a Class III medical device, or introduces a new or modified version/model of the same device, either an amended or new design dossier must be prepared, reviewed by the CAB and an amended or new certificate must be issued.

Unlike Class IIb medical devices, Class III devices are controlled to the individual product level. This allows appropriate post-market monitoring, tracking and recall where necessary and thus provides not only improvements to pre-market evaluation, but improves the TGA's regulatory oversight once these prostheses are on the market.

## **International Regulation and Review of Joint Replacement Implants**

As further background, a review of regulatory requirements and pre-market assessment requirements of orthopaedic joint implants in equivalent international regulatory jurisdictions is provided as Attachment 2 to this paper.

## ***The Consultation process***

### **Questions for consideration**

With the publication of this paper, the TGA is requesting comment from interested parties on the proposal described herein. In particular, comment is sought on –

- The intention to increase the degree of pre-market review considered appropriate to ensure orthopaedic joint replacement implants approved for marketing in Australia are in compliance with the Essential Principles (of safety and performance) and have adequate clinical evidence to substantiate claims made by the manufacturer for device performance.
- The intention to include partial implants in the re-classification of orthopaedic joint implants.
- Any alternative options to that proposed in order to address issues identified in this paper.
- Any likely impact on devices currently supplied, or planned for supply to the Australian market.
- The proposed transition arrangements.

### **Invitation to comment**

Relevant industry sectors, professional and consumer groups are invited to provide comment and input to the consideration of a proposal to re-classify joint replacement implants supplied in Australia.

The TGA is inviting submissions, views and input from all interested parties by close of business on **Friday 4 December 2009**. All interested parties are welcome to provide input to this consultation process.

The TGA will use the submissions and input received to help inform future regulatory directions.

Once the consultation period has closed, the TGA will continue to work with stakeholders in formulating the final direction in this matter.

### **Please forward all consultation feedback to:**

Parliamentary and Management Group  
Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

**or** Parliamentary and Management Group  
Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
136 Narrabundah Lane  
SYMONSTON ACT 2609

Or via **email** to: [ODBTConsult@tga.gov.au](mailto:ODBTConsult@tga.gov.au)

### **Please note:**

A list of names of parties making submissions will be published on the TGA website.

All submissions will be placed on the TGA's website. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's website. Confidential material contained within submissions should be clearly marked. Reasons for a claim to confidentiality must be included in the submission coversheet.

Where possible confidential material will be redacted from information published on the TGA website.

This document is intended to be a consultation document and should therefore not be relied upon for advice regarding the regulation of medical devices.

## ***Attachment 1***

### ***Essential Principles***

The Essential Principles (EP's) set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with medical device standards is not mandatory, but is one mechanism under the framework for a manufacturer to establish compliance with the EP's.

The Essential Principles may define, for example, results to be achieved, performance levels, hazards to be addressed, or issues to be considered, but do not specify how the principles can be satisfied or complied with.

This provides flexibility for a manufacturer and caters for technology advances and changes in the application of medical devices.

The Essential Principles can be divided into two main types:

- general principles - which always apply to all medical devices; and
- particular principles - which only apply to some medical devices.

It should be noted that **both** the general principles **and** the relevant particular principles have to be met in order to meet the requirements of the Essential Principles for all medical devices. Compliance with only the relevant particular principles does **not** ensure compliance with the general principles.

It is the responsibility of a manufacturer to demonstrate the medical device is in compliance with the applicable Essential Principles.

Further information on the Essential Principles can be found in TGA's *Guidance Document 22 – The Essential Principles for medical devices*, <http://www.tga.gov.au/docs/html/devguid22.htm>

## **Attachment 2**

### **International Regulation and Review of Joint Replacement Implants**

#### **Europe**

When the Medical Devices Directive 93/42/EEC was introduced in 1993, joint replacement implants, along with most other permanent implantable devices, were designated as Class IIb medical devices.

In 2005, the European Commission issued Directive 2005/50/EEC amending the classification of knee, hip and shoulder joint replacement implants from Class IIb to Class III medical devices. This directive made provision for a transition period for manufacturers, with various deadlines, ultimately finishing in September 2010.

The reclassification was brought about at the instigation of both the United Kingdom and French Competent Authorities, citing some of their concerns<sup>5</sup> such as:

- complexity of the functions of the joint functions to be restored, and the consequent increased risk of failure due to the device itself,
- these joints are weight bearing and extremely sophisticated implants for which the risk of revision surgery is significantly greater than for other joints,
- shoulder implants are a more recent introduction, subject to similar dynamic forces and their possible replacement is, in principle, connected with serious medical problems,
- hip, knee and shoulder replacement surgery is increasingly being undertaken on younger patients with a consequently higher life expectancy. This has resulted in the need to reduce the risk associated with revision surgery by ensuring such implants function properly over the life expectancy of the patients.

However, the major concern of the proponents for reclassification, which was also supported by other Competent Authorities, was that specific, long term clinical data was generally not always available before these devices were placed on the market. As a consequence, it was argued that supporting clinical evidence generated by the manufacturers of such devices should be subject to more rigorous scrutiny to ensure it was both appropriate and sufficient to support the manufacturer's Declaration of Conformity with the Essential Requirements.

Further concerns were also expressed that, even when changes to devices were incremental and considered 'minor' by the manufacturer, there have been a number of instances where device performance has suffered as a result of these minor changes.

To minimise any clinical impact with the introduction of new technologies, new implants or changes to existing implants and reduce the design related problems to the lowest level, the classification of these implants was changed to Class III in 2005, with the transition to full implementation of the reclassification to be completed by September 2010.

The reclassification is applicable to all implantable components which are parts of a load bearing total joint replacement system intended to provide a function similar to a natural hip,

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<sup>5</sup> The concerns enunciated by both the United Kingdom and France are incorporated in the opening text of the European Commission Directive 2005/50/EEC on the re-classification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC on medical devices. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:210:0041:0043:EN:PDF>

knee or shoulder. These components may be placed on the market either singularly with the intent of being assembled in to a specified total joint system, or as a complete total joint replacement including all component parts and accessories.

The word ‘total’ is interpreted as meaning to replace both opposing articulated surfaces of the joint. Uni-compartmental knee components and hip resurfacing devices fall within the scope of the reclassification as these devices replace both articulating surfaces.

Partial joint replacements, such as hip hemi-arthroplasties, are excluded from the reclassification, as are ancillary components such as screws, plates wedges and instruments.<sup>6</sup>

This change now requires CABs to assess a design dossier for these products, including the clinical data used by the manufacturer to support the claimed performance, and any subsequent post-market design and manufacturing changes must also be reviewed in detail before introducing the device into clinical use.

## **Canada**

Canada, like Australia, has a regulatory system based on the principles of the GHTF. Both total and partial joint replacement implants in Canada are considered Class III medical devices, the equivalent of Australia’s Ib classification.

However, unlike Australia, an application for a device licence for either a new Class III device or a new or modified version/model of the same Class III medical device must be accompanied by the equivalent of a technical dossier including details and key specifications of the device, its intended use in clinical practice, labelling and a summary of all studies used by the manufacturer to support their conclusion the device meets the safety and effectiveness requirements.

Applications for Canadian Class IV (equivalent to Australian Class III) medical devices must be accompanied by a more comprehensive dossier, constructed broadly in line with the requirements of the GHTF STED. The additional information required includes a documented risk assessment, details of manufacturing processes and validation studies, and a summary of all studies (both clinical and pre-clinical) used by the manufacturer to support their conclusion that the device meets the safety and effectiveness requirements.

In both instances the dossier is reviewed by Health Canada prior to issuance of a licence and approval for marketing.

## **United States**

The USA is a member of, and active participant in the GHTF, but has not yet been able to apply the full GHTF risk classification to its existing medical device legislation.

In lieu of a risk based classification system, the US Food and Drug Administration (FDA) places all medical devices into one of three regulatory classes based on the level of control necessary to ensure safety and effectiveness of the medical device:

- Class I            General Controls
- Class II            General Controls and Special Controls

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<sup>6</sup> Guidance issued by the UK Medicines and Healthcare Products Regulatory Agency on the Commission Directive on the Re-classification of Total Hip, Knee and Shoulder Joint replacements, see <http://www.mhra.gov.uk/Howweregulate/Devices/MedicalDevicesDirective/Classification/CON009794>

- Class III            General Controls and Pre-market Approval.

This classification designation is risk based, Class I being considered the lowest risk and Class III the highest, but, unlike the GHTF risk based classification system using rules, the FDA assigns the classification based on device type and publishes the risk class in the Code of Federal Regulations.

Both total and partial hip, knee and shoulder implants, are classified as either Class II or Class III medical devices depending on factors such as technology maturity, fixation method, materials, post-market experience, etc.

*Special Controls* may include:

- Specific labelling requirements
- Compliance with mandatory or voluntary performance standards
- Post-market surveillance activity requirements
- Other requirements outlined in device type specific guidance documents.

In common with the GHTF regulatory model, more regulatory scrutiny is applied to a medical device as the risk presented by the device increases.

*Pre-market approval* is required where the FDA does not consider sufficient information exists in the general domain to assure safety and effectiveness solely through the application of general or special controls. This is the process of review by the FDA, of technical, scientific and clinical data generated and provided by the manufacturer to demonstrate the safety and effectiveness of the device. Most, but not all, Class III devices require pre-market approval.

The alternative review process, referred to as *510(k) review*, requires a device manufacturer to demonstrate a new device is *substantially equivalent* to an already existing device in the market. To achieve this, the manufacturer must compile a technical dossier, broadly in line with the requirements of the GHTF STED, for review prior to marketing approval being granted.

## **Japan**

The Japanese regulatory framework embodies the GHTF principles of compliance with essential principles of safety and performance, risk based classification of devices and application of an appropriate conformity assessment procedure by the manufacturer, to the device and the manufacturing process.

Both total and partial hip, knee and shoulder implants are classified as Class III medical devices, the equivalent of Australia's IIB classification.

All high risk Class III and Class IV (equivalent to Australian Class IIB and III respectively) devices, and all new medical devices for which there is no substantially equivalent predicate, regardless of classification, are assessed by the Pharmaceutical and Medical Devices Authority before a report and recommendation for approval is provided to the Ministry of Health Labour and Welfare.

