TGA Therapeutic Goods Administration

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Commonwealth Department of
Health and
Family Services

19/6
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Dr Ronald Sekel
Portland Square Pty Ltd
St George Private Hospital Medical Centre
Suite 3, Level 5
1 South Street
Kogarah NSW 2217

Dear Dr Sekel,

Thank you for your call yesterday regarding the conformity assessment of the Portland Square Margron Total Hip Replacement. I confirm the following:

- If Portland Square is placing the device on the market in the European Union and has the responsibility for design and manufacture, then Portland Square is defined as the manufacturer for the purposes of the Medical Devices Directive (MDD).

- For a Class IIb product, the manufacturer must have an appropriate EN46001/ISO9001 or EN46002/ISO9002 quality system as required by Annex II or Annex V of the MDD.

- If the Annex II route is chosen then the manufacturer must be able to demonstrate that the application of the quality system, or controls that were in place at the time of design. The controls are to ensure that products conform to the provisions of the MDD which apply to them at every stage, from design to final inspection.

I have attached an extract from "The Medical Device Directives – A Manufacturer's Handbook" by Gordon Higson. It provides some guidance as to the choice of the conformity assessment route that should be used by a manufacturer.

I look forward to meeting with you. Please don't hesitate to contact me if you require further assistance (02) 6232 8704.

Yours sincerely,

Keith M Smith
Manager, Conformity Assessment Services
Conformity Assessment Branch
23 February, 1999

vi) Factors Influencing the Choice of Conformity Assessment Procedure

Design assurance by quality system (Annex II)

For	Against
Periodic plant inspections are valid for all products.	Time and cost of introducing design control procedure.
New products (within the same general group) can be introduced without Notified Body intervention (except Class III).	Resistance of design/development personnel to "bureaucratic" systems.
Audits cover both design and production.	
Product modifications can be introduced without Notified Body intervention (except Class III). EN ISO 9001 certification may be a good marketing tool.	
Quality system should improve design procedures.	
A quality system corresponding to EN ISO 9001/EN 46001 is required by other countries where the device may be marketed, such as USA and Japan.	

Design assurance by type examination (Annex III)

For	Against
Existing test reports may be sufficient.	Every type of product needs individual examination.
Type testing procedure may be familiar.	Possibility of queues at Notified Body
Possession of test house marks may be good marketing tool.	Product changes must be negotiated with Notified Body.
	Separate control of production is needed.

From this analysis it can be seen that a manufacturer of a wide range of products, or products subject to frequent change, would find the quality system approach advantageous, whereas a small manufacturer, or a manufacturer of products already subjected to type testing under current regulations, would find type testing to be preferable.

Production assurance

Similar considerations affect the choice of production assurance methods. A small manufacturer, with a limited range of products, may find it simpler to submit to sample testing than to initiate a formal quality system, although this decision might be coloured by economic considerations related to the sampling ratio and the geographical proximity of the Notified Body.

Large manufacturers would find that a quality system, with its routine of periodic surveillance inspections, would be less trouble than sampling tests on a range of products. For Class IIa and IIb medical devices, a product quality system (ISO 9003 equivalent) is permitted. This is less demanding than a production quality system (i.e. ISO 9002 level) but its use might be qualified by factors such as the lower level of assurance offered by this system, and its general lack of familiarity and widespread acceptance. It should also be borne in mind that the product quality system is not suitable for sterile products.

vii) Special Provision for Drug/device Combinations

All devices incorporating a medicinal product and subject to Essential Requirement 7.4 fall into Class III and must therefore be assessed by either the procedure of Annex II (including the design dossier examination) or that of Annex III. Both Annexes include the provision that when such a device is being assessed "the Notified Body shall ..... consult one of the competent bodies established by the Member States in accordance with Directive 65/65/EEC before taking a decision".

Commission Guideline 14/93 (see Appendix 5) describes the procedure to be followed by the NB and lists the competent bodies in each Member State.

viii) Things to Bear in Mind

- It is essential to be sure about the classification of devices before deciding on a conformity assessment procedure.

- It may be more efficient to operate one conformity assessment procedure throughout a manufacturing plant, even though this procedure may be more rigorous than strictly necessary for some products. This is particularly the case where quality systems form the basis of the procedures.

- Tests and assessments carried out under current national regulations can contribute towards the assessment of conformity with the requirements of the Directives.