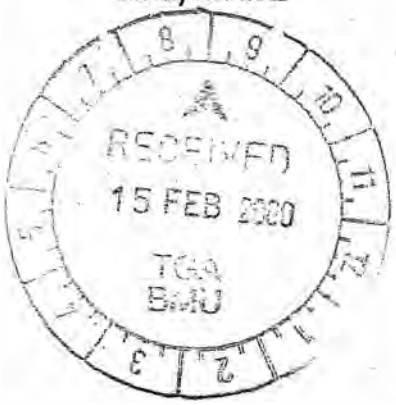
Brazenor Device.

TGA THERAPEUTIC GOODS ADMINISTRATION

Commonwealth Department of Health and Family Services



Therapeutic Devices Application

(Australian Register of Therapeutic Goods)

Use this form if you are applying for:

- Registration of Therapeutic Device(s)
- Listing of Therapeutic Device(s)
- Addition to either a Registration or Listing of a Therapeutic Device
- Variation to either a Registration or Listing of a Therapeutic Device
- Transfer of a device between the listed and registered categories

May 1998

Th131550

It is the sponsor's responsibility to ensure that this form is accompanied by adequate data for evaluation (Registrable Devices) or all relevant documentation (Listable Devices) and includes the appropriate application fee.

INCOMPLETE APPLICATIONS WILL BE REJECTED.

What to do if you encounter problems

- consult the notes contained in this form. They appear opposite the relevant question,
- The TGA regulatory manual *"Australian Medical Device Requirements – DR4"* should be consulted when completing this form.
- The *"Therapeutic Goods Act 1989"*, *"The apeutic Goods Regulations"* and Therapeutic Goods Orders (TGO) are available from Government Info Shops, Phone 132 447, website http//:www.agps.gov.au
- for specific problems contact the Medical Devices Information Officer or the TGA Publications Office on 1800 020 653 or facsimile (02) 6232 8687, website http://www.health.gov.au/tga.

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1 Sponsor's business name

a) if a corporation:
   – the registered company name
   eg Aussie Medical Supplies Pty Ltd, or
b) if an individual trader:
   – the full name of the person conducting the business
   eg John Melbourne Smith, or
c) if a partnership:
   – the full names of both/all partners conducting the business
   eg John Melbourne Smith and Mary Brisbane Brown, or
d) if trading under another business name:
   – if appropriate, give any other trading name or abbreviated name in brackets after the above name
   eg John Melbourne Smith (Aussie Medical Supplies), or
   Aussie Medical Supplies Pty Ltd (AMS)

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2 Sponsor's address

Please complete this question with your street address.

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3 Enterprise I.D. code

If you are not aware of your Enterprise Identification Code, please contact the Operations Manager, ARTG, on (02) 6232 8590 for advice. If you have not been allocated a code leave this item blank and complete a separate *"Enterprise Details"* form, available from the TGA Publications Office on 1800 020 653.

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6 Signature of authorised person

The Declaration must be signed by a person who has submitted an Enterprise Details form. This person must be either a sponsor, company director or company secretary of a sponsor or the sponsor's duly appointed agent (e.g. employee or consultant) who is authorised to provide information and to make declarations for the purposes of applications as required under the *"Therapeutic Goods Act 1989"*.

If signed by the sponsor's duly appointed agent please attach a copy of the *"Instrument of Appointment"* for that agent. If another agent is appointed a fresh *"Instrument of Appointment"* must be submitted to the Operations Manager, ARTG. The *"Instrument of Appointment"* is included under Section D of the *"Enterprise Details"* form.

Sponsor details (*all applicants to complete*)

1. **Sponsor's business and trading name** *(refer note opposite)*: DEPUY Australia Pty Ltd a Johnson & Johnson Company

2. **Sponsor's address**: 20 - 24 Howleys Road Notting Hill
Victoria 3168

3. **Has an *"Enterprise Details"* form previously been submitted:** *(refer note opposite)*

(i) for this business? Yes ☑ No ☐

If **Yes**, give the Enterprise I.D. code: 10330

If **No**, please complete an *"Enterprise Details"* form and submit it with this application.

(ii) for the authorised person? Yes ☐ No ☐

If **No**, please complete an *"Enterprise Details"* form, Section D, and submit it with this application.

4. **Authorised Person's/ Authorised Agent's for this application**: PETER WITHERSPOON

5. **Authorised Person's/ Authorised Agent's telephone number**: (03) 95626166 **Facsimile number**: (03) 95626161

Agent's name:

Agent's address:

6. **Declaration *(all applicants to complete)***

Sponsors should note the *"Therapeutic Goods Act 1989"* provides penalties for making statements that are false or misleading in connection with an application for registration or listing of therapeutic goods.

I declare that the information given is current and correct.

Signature of authorised person *(refer note opposite)*: Peter Witherspoon

Date: 14 / Feb / 2000

Name *(please print)*: PETER WITHERSPOON

Your position/title/office in relation to sponsor: REGULATORY AFFAIRS MANAGER

Commercial - in - Confidence

7 **Is this device for export only?** Yes ☐ No ☑

☐ **I am applying for**
(refer note opposite)

Registration of Therapeutic Device(s)	☐	
Listing of Therapeutic Device(s)	☑	
Addition of product(s) to an existing Registration	☐	Specify AUSTR number
Addition of product(s) to an existing Lisitng	☐	Specify AUSTL number
Variation to existing Registration/Listing	☐	Specify AUSTL/R number
ARTG transfer	☐	Specify AUSTL/R number

Variation details *(only applicants varying details of a registration or listing to complete)*

9 **Category of change**
(give a brief description)
(refer note opposite)

10 **Application fee**
(refer note opposite)

A $ 300

Manufacturer Release for Supply

The manufacturer who carries out final inspection and testing as required in Clause 4.10.4 of ISO9001/2 (which forms the basis of EN 46001/2 and ISO 13485/88) as part of the quality plan and/or documented procedures required by Clause 4.2 ISO9001/2 to complete the evidence of conformance of the finished product to the specified requirements.

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12 **Licence number**

Australian manufacturers of therapeutic devices included in items 4 and 5 of Schedule 7 of the Regulations are required to be licensed. Please see Explanatory note 23 for products which require licensing.

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14 **Manufacture's site address**

The actual manufacturing site address. Where applicable the address for which quality systems/GMP certification (as specified in the Manufacturing Principles of the *Therapeutic Goods Act 1989*) is issued needs to be stated.

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16 **Step(s) in manufacture**

Give all manufacturers involved in the key steps of manufacture of the device **(do not include component or material manufacture)**.
Key steps are:

- quality assurance/GMP and release for supply;
- manufacture;
- testing;
- design;
- processing;
- assembly;
- packaging, labelling;
- sterilisation.

If the manufacturer performs the full manufacturing process write "full".

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17 **Manufacturer's name**

If the manufacturer nominated in answer to question 11 has only a partial role in manufacture, please give details of all manufacturers for other key steps as listed above.

If there are more than two manufacturers, turn to page 33.

Manufacturer details - release for supply

11 **Manufacturer's name** DEPUY ACROMED INC.

12 **TGA Licence number** *(Aust manufacturers only)* *(refer note opposite)* **Has licence been applied for?** Yes ☐ No ☐

31232

13 **Manufacturer's Enterprise I.D.** *(if known)* 31232 - TH

14 **Manufacturer's site address** *(refer note opposite)* 325 Paramount DRIVE
Raynham, MA - 02767 : USA.

15 **Manufacturer's postal address** *(if different to above)* AS ABOVE

16 **Step(s) in manufacture** *(refer note opposite)* Manufacture & Release (Full)

If 'FULL' go to question 22

Other Key Step Manufacturers *(refer note opposite)*

17 **Manufacturer's name** *(refer note opposite)*

18 **Manufacturer's Enterprise I.D.** *(if known)*

19 **TGA Licence number** *(Aust manufacturers only)* **Has licence been applied for?** Yes ☐ No ☐

20 **Manufacturer's site address**

21 **Step(s) in manufacture**

Manufactured goods which require quality systems/GMP certification

- All registrable devices – Schedule 3.
- Listable devices covered in the Therapeutic Goods Regulations – Schedule 6 and items 4 and 5 of Schedule 7.

Examples of Listable Devices

- bandages and allied products
- blood bags
- blood collection tubes
- condoms
- contact lenses (soft)
- contraceptive devices
- dental restorative materials
- devices used for the prevention of transmission of disease.
- devices included as Pharmaceutical Benefits
- diaphragms (contraceptive)
- drainage bags
- gloves (examination or surgical)
- implants
- IVD's for home use
- IVD's of human origin
- lubricants for internal use
- non glass containers for blood or injection
- parenteral infusion bags
- sterile devices

Examples of Registrable Devices

- active implantable medical devices eg
  - implantable cardiac pacing systems
  - implantable pacing leads
- breast prostheses (implantable)
- contraceptive barrier devices (where no standard is available)
- devices of human or animal origin
- disinfectants with specific claims eg
  - hospital grade
  - household/commercial grade
  - instrument grade
- heart valves
- HIV & HCV in vitro diagnostic kits
- intraocular fluids
- intraocular lenses (except approved posterior chamber PMMA)
- intrauterine contraceptive devices
- drug infusion systems – powered (except some simple pumps)
- sterilants

Refer to the *"Standard of Overseas Manufacturers"* (current edition) for the acceptable forms of evidence to establish quality systems/GMP certification.

Evidence is required for all overseas manufacturers of goods specified above at the time of application, unless previously supplied. If you have already supplied acceptable documentation as part of a successful application for registration or listing of a product, this documentation may not need to be supplied again, if this is the case, insert the AUST R or AUST L number of that product in the form.

Overseas manufacturer - Quality Systems/GMP Certification
(registration and listing applicants to complete)

22 **Do the goods appear in the list opposite?**
(refer note opposite)

Yes ☑ **No** ☐ — *Go to question* **25**

If **Yes**, has evidence of quality systems/GMP certification for **each** manufacturer previously been accepted by the TGA?

Manufacturer 1
Yes ☑ No ☐

Manufacturer 2
Yes ☐ No ☐

Evidence must be no more than 5 years old and valid for at least 6 months at the time of applilcation

If **No**, attach evidence of quality systems certification *(refer notes opposite)*

Unavailable/unacceptable evidence of quality systems/GMP for overseas manufacturers

The *Therapeutic Goods Act 1989* requires that imported goods manufactured outside Australia comply with equivalent standards of manufacturing as expected for similar products manufactured in Australia. Applications may be refused on the following grounds:

(i) if the applicant does not provide an acceptable form of evidence from a relevant overseas authority to establish that the manufacturer of the goods is of an acceptable standard; and

(ii) if the applicant does not agree to provide funds for the TGA to carry out an inspection of the manufacturer and evidence that the manufacturer has agreed to such an inspection. This is required where the TGA considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary.

Compliance with Therapeutic Goods Orders or prescribed quality and safety criteria

List of applicable goods

- barium lime
- bandages, dressings aid allied products – non sterile (microbial count certificate required)
- catheters (urethral, single use)
- condoms (test certificate required)
- dental restorative materials
- diaphragms (contraceptive)
- disinfectants and sterilants
- gloves (examination and surgical)
- insulin syringes
- IVD's of human origin
- pyrogen/endotoxin free products
- sutures and ligatures
- tampons - menstral

Most Therapeutic Goods Orders (TGO) are available for purchase from Government Info Shops. If unavailable, contact TGA Publications office on 1800 020 653 or facsimile (02) 6232 8605. New TGOs introduced will be notified in the *"Australian Therapeutic Device Bulletin"*.

Test certificates must be from an acceptable test laboratory and must be signed and dated by the analyst.

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23 **If evidence unavailable/unacceptable, do you agree to pay the costs of inspection by Australian TGA Auditor if deemed necessary by the Secretary?**

Yes ☑ No ☐

If **No**, attach a separate sheet giving reasons.

24 **Has/have the overseas manufacturer(s) agreed to such an inspection?**

Yes ☑ No ☐

If **No**, attach a separate sheet giving reasons.

Compliance with Therapeutic Goods Orders or prescribed quality and safety criteria *(registration and listing applicants to complete)*

25 **Do the goods appear in the list opposite?** *(refer note opposite)*

Yes ☐ No ☑

If **Yes**, you must have available a current test certificate demonstrating compliance with each requirement of the relevant standard. Test certificates must be less than 2 years old.

Note: 1. For condoms and contraceptive diaphragms the test certificate must be from an independent laboratory and relate to a batch to be supplied in Australia and be submitted with the application.
2. For non-sterile bandages and dressings where the manufacturer does not have a certified quality system/GMP – a Site Information File together with a microbial count certificate less than 6 months old for the first batch to be supplied in Australia, is required with the application.
Test certificates are required to be submitted for the next five batches of product to be supplied in Australia, prior to these batches being supplied.

Specific Requirements for Electromedical Devices

It is the responsibility of sponsors to demonstrate electromedical equipment, submitted for listing on the ARTG, has been tested for compliance with an acceptable electrical safety standard and that the sponsor has documentary evidence in their possession at the time of listing to support the claim of compliance.

Risk classification is used to determine the appropriate level of testing required to demonstrate compliance. Please refer to *"Australian Medical Device Requirements under the Therapeutic Goods Act 1989 – DR4"* for further details.

Acceptibility of Certificates

- **Certificates issued within Australia by:**
  - A NATA or equivalent accredited organisation for the appropriate standard to which the certificate is issued; or
  - A State Government electrical approvals authority.
- **Overseas Certificates issued by:**
  - An organisation accredited to *EN 45001 – General Criteria for the Operation of Testing Laboratories;* or
  - A certificate of compliance with the IECEE-CB Scheme.

Electromagnetic Compatibility

The TGA requires compliance be demonstrated to *AS/NZS 3200.1.2 – 1995 – Approval and test specification – General requirements for safety – Collateral Standard: – Electromagnetic compatibility – requirements and tests* or AS/NZS 3200 part 2 standards applicable to specific items of equipment, and documentation be held by the product sponsor to support claims of compliance.

Is the device electrically powered? Yes ☐ No ☒

Complete both (a) and (b)

The sponsor of any electromedical device which is the subject of this application must retain documentary evidence in the form of a technical dossier which demonstrates compliance with the appropriate requirements below:

Note: Certificates are not required to be submitted with the application.

(a) Australia

☐ AS 3200.1 – 1990 – Approval and test specification – Medical electrical equipment – Part 1 – General requirements for safety

☐ AS 3551 – 1996 – Technical management programs for medical devices (applicable clauses)

☐ Certificate of Approval number _____ issued by _____ of _____ (State)

on _____ (Date)

☐ Certificate of Suitability number _____ issued by _____ of _____ (State)

on _____ (Date)

Overseas

☐ IEC 601.1 – 1988 – Medical electrical equipment – Part 1 – General requirements for safety

OR Equivalent

☐	EN 60601.1	Europe
☐	BS 5724	United Kingdom
☐	UL 2601	United States
☐	CSA C22.26 – 601	Canada

☐ Certificate of compliance with IECEE-CB Scheme

(b) Electromagnetic Compatibility

☐ AS/NZS 3200.1.2 – 1995 – Approval and test specification – General requirements for safety – Collateral Standard: – Electromagnetic compatibility – requirements and tests or AS/NZS 3200 part 2 standards applicable to specific items of equipment

☐ IEC 601.1.2:1993 – Medical electrical equipment – General requirements for safety – Collateral Standard – Electromagnetic compatability – Requirements and tests

☐ EN 60601.1.2:1993

Foreign approvals for Registrable Devices

27 **Has the product received prior approval from any other regulatory agency?** **Yes** ☐ **No** ☑

If **Yes**, indicate the type of prior approval
(Please attach separate evidence for each product)

US FDA Approval ☐	Pre Market Approval – PMA ☐	Date	
	Supplementary Pre-Market Approval – SPMA ☐	Date	
	Investigation Device Exemption – IDE ☐	Date	
	EC Design Examination Certificate ☐	Date	
	EC Type Examination Certificate ☐	Date	
	EC Quality Systems/GMP Certificate ☐		
Certification Agency		Approval date	
Type of Certificate *(refer note opposite)*		Expiry date	

Regulatory record *(registration and listing applicants to complete)*
(refer note opposite)

28 **Have any of the therapeutic devices included in this application been refused registration in another country or are subject to:**

- any bans from sale or supply, product recall or product correction? **or**
- investigation in relation to performance, quality, safety and efficacy? (excluding routine premarket evaluation) **or**
- further restrictions or conditions, relating to the fitness for use of these devices for certain purposes or categories of patients following supply? (other than normal indications and contra-indications in published product information).

by overseas regulatory authorities? **Yes** ☐ **No** ☑

If **Yes**, please attach details.

- **Sponsors must be aware of their post market responsibilities for this product. Post market responsibilities are set out in the Standard Conditions document issued to sponsors when their goods are included in the ARTG.**

30 **ECRI IMD code ©**

The medical device nomenclature and the five digit number associated with each medical device are part of ECRI's Universal Medical Device Nomenclature System, a widely employed international classification system of information indexing and retrieval. The five digit number is the authorised ECRI International Medical Device Code © (IMDC).

Refer to Appendix of DR4 or *"Australian Device Groups"* or if uncertain leave blank.

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31 **Brief description of product**

Provide a brief description of the intended use and function of the device.

Individual Product details *(registration and listing applicants to complete)*

If there are additional individual products included in this application, photocopy this page and submit with this form.

29 **Product trade name and model number(s) as it appears on the label**

Brazenor Device.

30 **ECRI IMD code ©** *(refer note opposite)*

15 766

31 **Brief description of product** *(refer note opposite)*

Anterior Fusion - Spine.

32 **Sterile Goods**

What product information has been sent with this application?

Unit labels	☑	(Compulsory for the initial application)
Outer package label	☐	(Compulsory for the initial application)
Package insert	☐	(Compulsory for goods sold over the counter)
Promotional material	☐	(Compulsory for goods sold over the counter)
Instructions for use	☐	(Compulsory for registrable devices, optional for listable devices)
User manual	☐	(Compulsory for registrable devices, optional for listable devices)
Brochure(s)	☐	(Optional but recommended)

33 **Non-Sterile Goods**

What product information has been sent with this application?

Outer package label or compliance plate	☑	(Compulsory for the initial application)
Package insert	☐	(Compulsory for registerable goods and for goods sold over the counter)
Promotional material	☐	(Compulsory for registerable goods and for goods sold over the counter)
Instructions for use	☐	(Compulsory for registrable devices, optional for listable devices)
User manual	☐	(Compulsory for registrable devices, optional for listable devices)
Brochure(s)	☐	(Compulsory for registrable devices, optional for listable devices)

34 Sterility

All products in this application must have the same sterility status.

Sterility status refers to whether the device or a component of the device is supplied sterile or non-sterile. If the device or its components, are supplied both sterile and non-sterile, two applications should be made.

Indicate more than one method if the device or its components are sterilised by alternative methods, eg a product which may be sterilised by gamma irradiation and a component by ethylene oxide.

Results of sterility testing must be held by the sponsor and made available on request by authorised person(s). Goods supplied sterile must be capable of demonstrating compliance with Therapeutic Goods Order No 11 – *"Standard for Sterile Therapeutic Goods"*.

It should be noted that Therapeutic Goods Order No11 – *"Standard for Sterile Therapeutic Goods"* is currently under review and will be revoked following adoption of the British Pharmacopoeia 1998 test method for sterility with additional guidance for sampling and testing of devices provided in the *"TGA Guidelines for Sterility Testing of Therapeutic Goods"*.

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35 Source of material

Indicate "Yes", if the product has been manufactured using material of human or other animal origin at any stage of its processing. Specify the species type of the material, eg:

- human
- bovine (cow)
- porcine (pig)
- ovine (sheep)
- other (specify)
- specify the country of origin of the human/animal material

Indicate "Not applicable", for devices which contain material of animal origin which are externally applied appliances that do not contact broken skin or mucous membranes, eg leather straps or sheepskin lined devices.

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36 Contact lens solutions, disinfectant/sterilant or hydrogel wound dressings proposed shelf life

The proposed shelf life should be based on stability data.

34 **Is this product or any of its components supplied sterile?** *(refer note opposite)* Yes ☐ No ☑

If **Yes,** indicate by what means

- Steam ☐
- Ethylene oxide ☐
- Filtration ☐
- Gamma irradiation ☐
- Glutaraldeyde ☐
- Dry heat ☐
- Electron beam ☐
- Other ☐

Please specify

35 **Was material of human or other animal origin used in the manufacture or formulation of this product?** *(refer note opposite)* Yes ☐ No ☑ N/A ☐

If **Yes,** give species type(s)

Specify country of origin of human/animal material

36 **Proposed shelf life of product**
(refer note opposite)

- 1 year ☐
- 2 years ☐
- 3 years ☐
- 4 years ☐
- 5 years ☐
- Other ☐

Please specify N/A

37 Contact lens solutions, disinfectant/sterilant or hydrogel wound dressings proposed storage conditions

Specify the proposed storage temperature for the product.

"Other" may include statements such as "Protect from light", "Do not freeze" etc. Terms such as "ambient temperature" or "room temperature" are not acceptable.

39 List of therapeutic goods contained in the Kit/Tray/Pack/System

Itemise all of the therapeutic devices contained in the kit, together with their appropriate ECRI IMD codes. It is not necessary to itemise contents which are exempt from registration or listing under Schedules 5 and 5A of the *"Therapeutic Goods Regulations"*.

For kits assembled with previously registered or listed therapeutic goods, itemise all products together with their respective AUST R/L number and the appropriate ECRI IMD code.

If more than ten components attach a list, or attach a photocopy of this question. For HIV and HCV kits itemise all the components of the kit. AUST R/L numbers and ECRI codes are not required for these in vitro diagnostic goods.

37 **Proposed storage temperature of product**
(refer note opposite)

store below 8 degrees Celsius (refrigerate) ☐

store at 2 to 8 degrees Celsius (refrigerate – do not freeze) ☐

store below 25 degrees Celsius ☐

store below 30 degrees Celsius ☐

Other ☐

Please specify N/A.

38 **Is this product a kit/tray/pack/system?** **Yes** ☐ **No** ☒ *Go to question* **40**

Kits, Trays, Packs or Systems *(registration and listing applicants to complete)*

39 **List of therapeutic goods contained in the Kit/Tray/Pack/ System**

	Description	AUST R or AUST L number	ECRI IMD code ©
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

40 Examples of medicated or formulated devices

Medicated Therapeutic Device is a device which is presented in combination with a drug but which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in function by such means.
Examples include:

- bone cements, bone cements with antibacterials
- catheters coated with drug eg heparin
- condoms with lubricant or spermicide
- gingival retraction cords combined with astringents
- intraocular lenses coated with heparin
- pacemaker leads containing or coated with drugs.

Formulated Therapeutic Device is a device which is usually presented as a gas, liquid, paste, gel or powder which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means.
Examples include:

- artificial saliva
- artificial tears
- barrier protectants for prevention of disease transmission
- collagen for injection, other injectable devices
- contact lens care preparations
- dental restorative materials
- disinfectants/sterilants
- hydrogel wound dressings
- intraocular and intrasynovial visco-elastic fluids
- lubricants
- ostomy cements and pastes
- refrigerant sprays
- skin and tissue adhesives

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41 Ingredients of medicated or formulated therapeutic devices other than contact lens solutions, disinfectants/sterilants and hydrogel wound dressings *

Use Australian Approved Names whenever possible. See *"TGA Approved Terminology for Drugs"*

Refer to *"TGA Approved Terminology for Drugs"* for units of quantity. Quantity (or strength) is required for registrable devices medicated devices and listable contact lens solutions, disinfectants/sterilants and hydrogel wound dressings.

Quantity is not required for formulated devices other than contact lens solutions, disinfectants/sterilants and hydrogel wound dressings.

If more than six ingredients attach a list.

* **Formulation details to be provided on supplementary page for contact lens solutions, disinfectants/sterilants and hydrogel wound dressings (page 23).**

Medicated or Formulated devices *(registration and listing applicants to complete)*

40 **Is this a medicated or formulated device?** *(refer list opposite)*

Yes ☐ No ☑

If contact lens solution, disinfectant/sterilant or hydrogel wound dressing go to question 42

41 **Ingredients of medicated or formulated devices other than contact lens solutions, disinfectants/sterilants and hydrogel wound dressings.** *(refer note opposite)*

Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	
Name	
Quantity	

Contact lens solutions, disinfectant/sterilant and hydrogel wound dressings active ingredient(s)

List all active ingredients plus the quantity of each. Use Australian Approved Names (AANs) whenever possible. A list of AANs appears in the *"TGA Standard Terminology"*. If the substance is not in the list of AAN, please provide sufficient details (using the form provided at the beginning of the list) so that an approved name can be derived. Standard terminology is essential for the ARTG to be able to provide accurate searches.

If an active ingredient is sourced from a proprietary ingredient, enter details of the active at question 42, any excipient substances at question 43 and details of the proprietary ingredient itself at question 44.

Checklist

Where requested, have you provided the following:

- [ ] "Enterprise Details" form – if not previously submitted.
- [x] Cheque for the applicable fee in Australian dollars.
- [ ] Additional pages of manufacturers.
  If so, how many manufacturers are included in this application? [ ]
- [ ] Evidence of quality systems/GMP certification for overseas manufacturers included in this application (if applicable).
- [ ] Copy of a current "Test Certificate" (where required).
- [ ] Supplementary page(s) for contact lens solutions, disinfectant/sterilant and hydrogel wound dressings formulation details (if applicable).
- [ ] Additional pages of individual product details.
  If so, how many individual products are included in this application? [ ]
- [x] Product literature or sample **(for sterile products please supply outer and unit pack labels).**
- [ ] Details of regulatory record (if applicable).
- [ ] Details of material supporting variation (if applicable).
- [ ] Copy of "Instrument of Appointment" (if applicable). (see Enterprise Details form)
- [ ] Evaluation submission (if applicable) as per *"Australian Medical Device Requirements under the Therapeutic Goods Act 1989 – DR4"* for Registrable devices.

Send the complete form, together with the application fee and attachments to:

The Business Manager
Business Management Unit
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If this is an application for Registration of a Therapeutic Device send the original application to the address above and a copy with your submission for evaluation to:

Postal address

The Premarket Evaluation Manager
Medical Devices Section
Conformity Assessment Branch, TGA
PO Box 100
WODEN ACT 2606

Courier address

The Premarket Evaluation Manager
Medical Devices Section
Conformity Assessment Branch, TGA
136 Narrabundah Lane
SYMONSTON ACT 2609

It is the sponsor's responsiblility to ensure that this application is accompanied by all relevant documentation and if the application is for a registrable device, adequate data. This includes the appropriate application fee(s).

Applications which are incomplete or contain incorrect information are liable to be rejected under Subsection 23(2) of the *Therapeutic Goods Act 1989.*

Office use only

Sponsor Enterprise I.D. ____

Receipt number ____ TGAIN ____

Amount received ____ ARTG No. ____

	Drug	Device
ADG Code ____ Defn	N	Y
Data		Y

GMP AC Yes ☐ No ☐

Test Cert AC Yes ☐ No ☐

LAB AC Yes ☐ No ☐

PM AC Yes ☐ No ☐

Product number ____

+H761PSB17190P

+$$9000017XXXXXP0

Manufactured For: REF PSB-1719

DePuy AcroMed™ LOT XXXXX QTY 1

Raynham, Massachusetts 02767, USA

Special Product

BRAZENOR DEVICE MATL T

CAUTION: USA Law restricts this device to sale by or on the order of a Physician. See package insert for labeling limitations.

⚠ NON STERILE

Authorized European Representative: AcroMed b.v., Rotterdam, The Netherlands

lubar JD 29/3/00