TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8704 Facsimile: (02) 6232 8785

CONFORMITY ASSESSMENT UNDER THE EU/AUSTRALIA MRA[a]

PRE-ASSESSMENT FORM

MANUFACTURER'S CONTACT DETAILS			
MANUFACTURER NAME:	Portland Orthopaedics Pty.Ltd	ACN:	001 243 434
CONTACT NAME:	David Sekel		
ADDRESS:	3/44 McCauley St Matraville N.S.W 2036	TGA ENTERPRISE NO:	151126
TELEPHONE:	FACSIMILE:	EMAIL:	
(02)9666 8444	(02)9666 8544	Davidsekel@marqron.com	

Notes to the Manufacturer:

1. This form is not an application for conformity assessment by the TGA. Information from this form will be used to estimate the costs to undertake conformity assessment of the product(s) nominated (Note 1).

2. The TGA cannot perform assessment of a product if an application is currently lodged with any other Notified Body for the same product testing or product-related quality system.

TGA will expect that (Note 2):

3. The manufacturer has read and understood the Medical Devices Directive (MDD - 93/42/EEC) or the Active Implantable Medical Devices Directive (AIMDD - 90/385/EEC) as applicable.

4. The obligations imposed by the product related quality system, if approved, will be fulfilled.

5. The product related quality system, if approved, will be kept adequate and efficacious.

6. A systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action will be instituted and kept up to date.

7. The Competent Authorities (Note 6) and the TGA will be notified of the following incidents immediately on learning of them:

   (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health

   (b) any technical or medical reason connected with the characteristics or performance of a device leading; for the reasons referred to in subparagraph (a), to systematic recall of devices of the same type by the manufacturer.

8. Where duly justified, the TGA will be provided with any information or data that is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

[a] MRA – Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

PRODUCT DETAILS

1. Device Details:

Product Name	Unique Identifier	Aust R/L No
1. Margron Hip Replacement System	See Appendix B - Catalogue sheets	53760
2.		
3.		
4.		

2. Intended use and how it is achieved:

The Margron Hip Replacement System is intended for primary or revision restruction, without bone cement, of the femoral portion of a severely disabled or very painful hip joint, where radiographic evidence of sufficient sound bone is present.

The Margron Femoral Stem is a modular prosthesis consisting of :
* A tapering stem cone with two different speed external threads and longitudinal derotation columns.
* A neck component which allows the optimum angle of anteversion to be selected after stem insertion.
*A modular stem extension component

3. Device Classification - Choose one (✓):

Class	☐	☒	☐	☐	☐	☐
	III	IIb	IIa	AIMD	I (sterile)	I (measuring function)

4. Annexes chosen by the manufacturer for the conformity assessment (✓):

MDD Annex(es)	☒	☒	☐	☐	☐	☐	☐	Have any of the following QAS Standards been implemented?			
(See MDD Article 11)	II.3	II.4	III	IV	V	VI	VII	ISO9001	☐	EN46001	☒
AIMDD Annex(es)	☐	☐	☐	☐				ISO9002	☐	EN46002	☐
(See AIMDD Article 9)	2	3	4	5				ISO9003	☐		

5. Accessory and/or system components and their interaction:

Accessory / System Component	Interaction / Function	Already CE Marked? (✓) Y	N
1. Margron Instrument Set	Used for the implantation for the device into patient. Includes tools, trials and templates.	☐	☒
2.		☐	☐
3.		☐	☐
4.		☐	☐

6. The device technology used (materials, components etc):

The Stem Component is machined medical grade cobalt chrome(CoCr) with a coating of hydroxyapatite.
The Neck component is forged and machined from medical grade CoCr.
The modular extension component is machine grade CoCr with a coating of hydroxyapatite.

MANUFACTURING DETAILS

1. Manufacturer activities and technologies performed/used at this site:

Contract Manufacturing
Machining
Finishing

2(i) Additional/sub manufacturers:

Manufacturer #1 - name & site address	Manufacturer #2 - name & site address
Vimek Pty.Ltd. 3/44 McCauley St Matraville N.S.W 2036	Steritech 5 Widemere Rd Wetherill Park NSW 2164

2(ii) Additional/sub manufacturers:

Manufacturer #1 - activities & technologies at this site	Manufacturer #2 - activities & technologies at this site
Contract Manufacturing Machining Finishing	Sterilisation (Radiation)

* If more than 2 extra manufacturers, please attach relevant details to the application

ADDITIONAL QUESTIONS	✓ Y	✓ N
1. Has technical documentation been prepared to show that the product complies with the relevant essential requirements of the directives?	☒	☐
2. Has a risk analysis been completed for the product?	☒	☐
3. Has clinical data been prepared in accordance with Annex X (MDD) *or* Annex 7 (AIMDD)	☒	☐
4. Will you require ISO9001/EN46001 or ISO9002/EN 46002 Certification?	☒	☐
5. Are the products covered by this application currently included in the Australian Register of Therapeutic Goods (ARTG)?	☒	☐

ATTACHMENT CHECK LIST	
Please attach the following to this application	✓
1. Risk analysis for each of the products concerned.	☒
2. An Essential Requirements Checklist indicating a) MDD/AIMDD Annex 1 essential requirements that have or have not been applied. Where an essential requirement has not been applied, the reason why it has not been applied.	☒
b) MDD/AIMDD Article 5 Standards, European Norms, International Standards, European National Standards and Third Country Standards or Manufacturers standards that have been applied.	☒
3. Quality Manual.	☒
4. Evidence of existing ISO9001(2) or EN46001(2) Certification.	☒
5. Declaration of Conformity Assessment of accessories or system components that have a CE mark.	
6. Evidence of assessment of product at an intermediate stage – Article 11(7), Article 9(5).	☐
<u>If applicable</u> 7. Copies of Annex III (MDD) or Annex 3 (AIMDD) certificates.	☐

NOTES

1) On review of the above information the TGA will provide an estimate of costs to undertake Conformity Assessment calculated from the current scale of fees and charges for technical documentation review and quality system audit.
2) A copy of the TGA's standard contract for Conformity Assessment services and details of the format for a formal application will accompany the estimate.
3) A technical meeting may be required to complete the pre-assessment.
4) The applicant should allow 5 days for the provision of an estimate. This time may be increased if the requested information has not been provided in full.
5) This form does not bind the applicant to use the TGA as the Conformity Assessment Body.
6) Please refer to the MDD 93/42/EEC for definitions of a Manufacturer, Notified Body and Competent Authority.
7) Under the terms of the MRA, the TGA cannot assess products which contain viable or non-viable material of Human or Animal origin.

Please provide an estimate of the time taken to complete this form [5] hrs [30] min

MANUFACTURING DETAILS

Subcontractor Cleaning & Packaging	A.S.D.M. 80 Bellingara Road Miranda NSW 2228 Australia Phone #: (61) 2 9522 2300 Fax #: (61) 2 9522 2311	Cleaning and Packaging
Subcontractor Hydroxyapatite Plasma Spraying	United Surface Technologies 26 – 32 Aberdeen Road Altona VIC. 3168 Australia Phone #: (61) 3 9398 5925 Fax #: (61) 2 9398 2738	Hydroxyapatite and plasma spraying
Subcontractor Forging	National Forge Pty Ltd 465 Somerville Road West Footscray VIC 3012 Australia Phone #: (61) 3 9314 9389 Fax #: (61) 3 9314 0200	Forging (necks)
Subcontractor Testing – Hydroxyapatite Coating	Centre for Advance Material Technology Monash University Clayton, VIC 3168 Phone #: (61) 3 9905 4741 Fax #: (61) 9905 4998	Testing Hydroxyapatite
Subcontractor Bioburden & Sterility Testing	AMS Laboratories Pty Ltd 118 Hattersley Street Rockdale NSW 2216 Australia Phone #: (61) 2 9567 8544 Fax #: (61) 2 9567 8228	Testing Bioburden and Sterility testing
Subcontractor Forging	Westray Engineering Pty Ltd 17-23 Captain Cook Drive Caringbah NSW 2229 Australia Phone #: (61) 2 9525 9333 Fax #: (61) 2 9526 1375	Forging (necks)