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TGA MEDICAL DEVICES

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TGA

THERAPEUTIC
GOODS
ADMINISTRATION

CONFORMITY ASSESSMENT BRANCH

2025/02

2026/02



IPU APPLICATION FORM

Mail: The clinical section, Conformity Assessment Branch, PO Box 100, Woden ACT 2606
 Fax: The clinical section, Conformity Assessment Branch (02) 6232 8785

Device

Name: Taylor Bryant Pty Ltd
 Model: MARGAN MINATURISED STEM 19mm ~~STEM~~
 Size: + MODULAR EXTENSION DIAMETER.
 Quantity: 2 COMPONENT. 6 or 7cm
 Supplier: PORTLAND ORTHOPAEDICS length.
 Name:
 Address: 44 McCauley St MATRIVILLE
 SYDNEY
 Phone: 02. 9. 666. 8444
 Fax:

Clinical Justification for using an unapproved device

Very small medullary canal in very small frame lady.
 + Tumour involving 10 cm of proximal femur
 for En Bloc Resection + Reconstruction.
 Current devices do not allow bulk allograft reconstruction
 of upper femur + Solid distal locking of prosthesis in bone.
 The Margan stem locking mechanism will allow more solid fixation
 + adjustability for leg length.
 (Where a currently approved device is available, indicate the advantages of the requested device)

Patient

Initials:
 Date of birth:

Procedure

Proposed date:
 Institution:

En Bloc Resection of Tumour @ femur + Reconstruction
 Total Hip Replacement.
 St George Private Hospital.

Doctor

Name: Ranskeel
 Address: 1 South St Kogarah Sydney.
 Phone: 95886399
 Fax: 9587 1014

Signature: Ranskeel

☐ Approved ☐ Not Approved

Signature: [Signature] 31/10/02

Please use proforma or replica thereof on your wordprocessor.

All enquiries should be directed to the administrative officer on phone (02) 6232 8679