

TGA

THERAPEUTIC
GOODS
ADMINISTRATION

PO Box 100 Woden ACT 2606 Australia
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Department of
**Health and
Aged Care**

* Extension *

Therapeutic Goods Act (1989) - Exemption from Registration

Notice of approval under Section 19(1)(a)

Individual Patient Use (IPU)

IPU No 3494/2001

EXPIRY DATE 15/2/02

Devices : 1.00 x Margron Mini Stem

Supplier : Ebos Health & Science Pty Ltd
PO Box 386
ALEXANDRIA NSW 2015

Fax : (02 9698 4535)

This formal notice of approval applies to the supply of the above device to:

**Dr Ronald Sekel
Medical Centre
St George Private Hospital
1 South Street
KOGARAH NSW 2217**

Fax : (02 9587 1014)

in the treatment of : [REDACTED]

subject to the following conditions :

1. The clinical use of the device is that stated in the application for approval;
2. The doctor and patient/guardian accept responsibility for the outcome of the therapy and the patient/guardian gives informed consent in the use of an unregistered device.
3. Details of adverse events with the use of the device are to be reported to the Therapeutic Device Incident Reporting Scheme;
4. The supplier will retain records of the distribution of the device for a period of at least 5 years;
5. The use of the device shall be regarded as experimental, and the principles set out in the National Health and Medical Research Council's Statement on Human Experimentation shall be observed;
6. Special conditions:

Detailed records of the procedure are kept, and the patient/guardian agrees to these records being included in any future clinical trial documentation.

Dr Martin Witenden-Devitt
Medical Adviser
Conformity Assessment Branch

Notification : Original to Ebos Health & Science Pty Ltd
Copy to Dr Ronald Sekel

16 November 2001