

28/08 '01 TUE 15:58 FAX +61 2 6232 8785

TGA MEDICAL DEVICES

TGA THERAPEUTIC
GOODS
ADMINISTRATION

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8615 Facsimile: (02) 6232 8785



Department of
**Health and
Aged Care**

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 27/11/01

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

IPU

☐ Approved ☐ Not Approved

Signature: _____

Date: _____

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

20 P. 02 16 NOV '01 16:00

[REDACTED]

John Green - Ebos

Op. 26/11/01.

Dr D. King

28 August 2001

16A

Professor Ronald Sekel

St George Private Hospital Medical
Centre Suite 3, Level 5
1 South Street
KOGARAH NSW 2217
AUSTRALIA

MBBS FRCSE FRACS (Orth)
ORTHOPAEDIC SURGEON

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Email: orthopaed@stgeorge.nsw.gov.au
Ronald Sekel Pty Ltd ACN 911 713 015

FACSIMILE TRANSMISSION SHEET

Date: 16/11/01 Routine () Urgent (✓) Confidential ()

Fax To: TGA

Attention: Health + Aged Care

From: Prof Ron Sekel

Fax No. 6232 - 8785

Number of Pages (including this) 2

If All Pages Not Received Contact: Faye

Comment: Re: IPU No: 3494/2001

Could we please have an extension on
this, as the surgery may be
postponed to a couple of days
after this date.

Thank you, Faye.