

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

TGA

THERAPEUTIC
GOODS
ADMINISTRATIONPO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8615 Facsimile: (02) 6232 8785Department 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	
<input type="checkbox"/> Approved	<input type="checkbox"/> 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 BranchNotification : Original to Ebos Health & Science Pty Ltd
Copy to Dr Ronald Sekel

P.02 16 NOV. 01 16:00

John Green - Ebos

Dr D. King

28 August 2001

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

Tel: (61-2) 9588 6399
Fax: (61-2) 9587 1014
Email: orthopad@acelpace.dcn.au
Ronald Sekel Pty Ltd ACN 011 713 015

FACSIMILE TRANSMISSION SHEET

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

Fax To: TGA

Attention: Health + Aged Care

From: Prof Ron Sekel

Fax No. 6232 - 8185

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.