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DOCUMENT 78

To: Bless Carter/TGA/Health, eBS Helpdesk,
Cc:
Bcc:
Subject: Gazettal Notification cancellation Nov 2011

Attached is a gazette notification of a cancellation limited to one specific device under the ARTG number. Please manage as per your process.

EBS - as the cancellation is limited to one device, as per section 41GO could you please vary the conditions of inclusion for the ARTG entry to exclude the device "Eska Adapter Femoral Stem Prosthesis"?

Thank you.

[redacted]
Executive Officer - Device Vigilance & Monitoring |Office of Product Review |Therapeutic Goods Administration
[redacted] url: www.tga.gov.au
Post: PO Box 100, Woden, ACT 2606 | Courier: 136 Narrabundah Lane, Symonston, ACT 2609

- Gazettal Notification cancellation Nov 2011.DOCX

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COPY

emailed 24/11/11
copy Dr Garcia

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

File Reference: 2011/011177

[redacted]
Eska Australia
Unit 32 A&B of 2-6 Chaplin Drive
LANE COVE NSW 2066
Australia

Dear [redacted]

Re: Gazettal notice for the cancellation of a product included under ARTG number 118441 – Eska Australia - Prosthesis, internal, joint, hip, femoral component – Eska Adapter Femoral Stem Prosthesis

I write to inform Eska Australia that a notice for the cancellation from the Australian Register of Therapeutic Goods of Eska Adapter Femoral Stem Prosthesis will be published in the Commonwealth Gazette within the first two weeks of December 2011.

As requested in your letter to the TGA dated 10 November 2011 the cancellation is limited to the device 'Eska Adapter Femoral Stem Prosthesis' only (see Therapeutic Goods Act, 1989, Section 41GO). Other devices also included under the above ARTG number, are not included in this cancellation. The devices not included are;

- GHE Femoral stem cementless standard offset,
- GHE Femoral stem cementless lateral offset,
- GHE/s Femoral stem cementless,
- GHE Femoral stem cementless for extension, and
- Femoral Cone cementless – revision.

The cancellation notice will be published in accordance with section 41GP of the *Therapeutic Goods Act (1989)* which requires the publication of cancellation notices in the Gazette to be undertaken as soon as practicable after the cancellation takes effect.

A copy of the notice to be published in the government Gazette is attached for your information.

Yours sincerely

[redacted]
Coordinator
Monitoring and Compliance Group
24 November 2011

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Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

PUBLICATION OF CANCELLATION OF ENTRIES FOR KINDS OF MEDICAL DEVICES FROM THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS SECTION 41GP OF THE *THERAPEUTIC GOODS ACT 1989*

I, Larry Kelly, delegate of the Secretary to the Department of Health and Ageing for the purposes of section 41GP of the *Therapeutic Goods Act 1989* (the Act), hereby publish particulars of the cancellation of the following entry of a kind of medical device from the Australian Register of Therapeutic Goods (the ARTG) under paragraph 41GN(1)(e) of the Act:

ARTG entry of kind of medical device: Eska Adapter Femoral Stem Prosthesis

ARTG number:	118441- Prosthesis, internal, joint, hip, femoral component
Sponsor:	Eska Australia
Date cancelled:	23 November 2011
Reasons:	The delegate of the Secretary under paragraph 41GN(1)(e) of the Act is satisfied that the safety or performance of the kind of device is unacceptable and under paragraph 41GO(1) the cancellation applies only to some medical devices of that kind included under this ARTG number.

[redacted]

Delegate of the Secretary to the Department of Health and Ageing

23 November 2011

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Minute

File No.2011/011177

[redacted]
Coordinator
Monitoring and Compliance Group

Notice of Cancellation – Gazettal Notice

Purpose:

To seek your approval for the product mentioned in the Notice of Cancellation of Inclusion to be Gazetted.

Issue:

- The safety and performance of the device is unacceptable.

Background:

- A Notice to Cancel has been sent to the sponsor.
- The time period from Notice to gazettal has expired.

Recommendation:

- Recommend that the Gazettal notice and letter to the sponsor informing them of the publication of the Cancellation be signed.

[redacted]
Director

23 Nov 2011

AGREED / NOT AGREED

SIGNED / NOT SIGNED

[redacted]
Group Coordinator
Monitoring and Compliance Group

Nov 2011

Office of Product Review
TGA
Delegate's Checklist

Note: This form must be completed for each individual decision of the Delegate and placed on the relevant file.

For use by Delegates with delegated authority
on behalf of the Minister or Secretary under:

Therapeutic Goods Act 1989 (Act)
Therapeutic Goods Regulations 1990 (Regs)
Therapeutic Goods (Medical Devices) Regulations 2002 (Device Regs)

Name of Recipient (to whom this decision relates): [redacted]

Company/business name (where relevant): Eska Australia

Submission/ARTG Number (where relevant): 118441 Adapter Femoral Stem Prosthesis' only

1. **Are you making this decision under the Act, Regs or Device Regs?** *(tick one)*

   Act [x] Regs [ ] Device Regs [ ]

2. **Under which Section or Regulation are you making this decision?** S41GO and 41GP

3. **Do you have a current delegation under that Section or Regulation?** Yes [x]

4. **Have you checked that all aspects and/or requirements of that Section/Regulation have been considered or met in making this decision?** Yes [x]

Delegate's name: [redacted]

Position number: 20002796

Signature: _____ **Date:** 24 **Nov 2011**