Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]

File Reference: 2012/021025

Eska Australia
72 South Street
RYDALMERE NSW 2116

Attention: [redacted]

DEVICE INCIDENT REPORT DIR 28523 - ARTG # 118430 - Prosthesis, internal, joint, hip, resurfacing

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within ten working days of the date of this letter**.

Responses should preferably be sent via email to iris@tga.gov.au, referencing the DIR number or alternatively by post or Facsimile on (02) 6232 8555.

If you are unable to respond with all the information requested immediately, please advise, **within the ten days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on (02) 6232 8695.

Yours sincerely

[redacted]

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

26/09/2012

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 26/09/2012

DIR: 28523 Manufacturer Name: Eska Implants GmbH and Co [45325]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number	**ARTG:**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	☐	☐
b) For Export	☐	☐
3) How many of this model have been supplied	In Australia:	
	Worldwide:	
4) How many of this batch (if applicable) have been supplied:	In Australia:	
	Worldwide:	
5) Are you aware of this problem, as reported?	☐	☐
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?	☐	☐
7) Have you had any other reports of similar problems with this product?	☐	☐

If **YES**, how many:

If **YES**, please give details:

8) If you are not the manufacturer, has the manufacturer been contacted for any other reports of similar problems with this product? ☐ ☐

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if ticked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:200

12) Additional Information required:

13) If your device is an implantable pacemaker/defibrillator you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.

Information Supplied By:

14) Name		Phone	
Signature		Fax	
Position		Email	

This questionnaire and any appended documents should be returned to the TGA within **10 working days.**

Attach your completed form to an **email** and send to: iris@tga.gov.au

Fax your completed form to: (02) 6203 1713

Supporting documentation following by normal mail
Please do not send more than one copy of your response to the TGA

Postal Address: Medical Device Incident Report Investigation Scheme, Office of Product Review - Devices, Therapeutic Goods Administration, **PO Box 100**, WODEN ACT 2606, Australia

Courier Address: Medical Device Incident Report Investigation Scheme, Office of Product Review - Devices, Therapeutic Goods Administration, 136 Narrabundah Lane, SYMONSTON ACT 2606, Australia

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed

DIR 28523 - ARTG # 118430 - Prosthesis, internal, joint, hip, resurfacing

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
13/09/2012

ARTG #:
118430

Brand Name:
Eska resurfacing ceramic hip replacement

Device Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Eska Implants GmbH and Co [45325]

Sponsor:
Eska Australia [45270]
72 South Street
RYDALMERE NSW 2116

Contact Name:
[redacted]

Phone: [redacted]

Email: [redacted]

Fax:

Reporter:

Confidential: Yes

Patient Outcome/Consequences:
Revision hip replacement.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Clinical Event Information:
Delamination of the ceramic coating causing early failure requiring revision procedure.