Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

[redacted]
ORTHOPAEDIC SURGEON

File Reference: 2012/021025

[redacted]

Dear [redacted],

DEVICE INCIDENT REPORT DIR 28523 - Eska resurfacing ceramic hip replacement

Thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Medical Device Incident Report investigation (IRIS) Database, where it will be evaluated against any previous incidents with the same or similar devices. A copy of the Device Incident Report (DIR) is attached for your reference.

We have also commenced an investigation into your complaint and contacted the product sponsor requesting details of any similar reports.

This process may take some time, but be assured we will advise you of the final outcome of our investigations. However, should you have any questions or further information, please contact me on (02) 6232 8695.

Thank you for your support of the Medical Device Incident Report Investigation Scheme.

Yours sincerely

[redacted]

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

26/09/2012

DIR 28523 - Eska resurfacing ceramic hip replacement

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

Sponsor:
Eska Australia
72 South Street
RYDALMERE NSW 2116

Contact Name:
[redacted]

Phone:
[redacted]

Reporter:

Confidential: Yes

Clinical Event Information:

Delamination of the ceramic coating causing early failure requiring revision procedure.

Patient Outcome/Consequences:
Revision hip replacement.

***** End of DIR 28523 *****