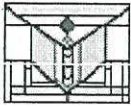


Will send report in the next
couple of days.

4
DOCUMENT 13

13



Fw: Prostheses Metal on Metal hip replacement- ESKA Australia
[SEC=UNCLASSIFIED]

Pamela Carter to: [REDACTED]

16/05/2011 12:15 PM

[REDACTED]
Has a report been received from Eska about this revision?

Thanks

Pam

Pam Carter

*Call
on Thurs.*

Director, Device Vigilance and Monitoring, Office of Product Review, TGA, PO Box 100, Woden ACT 2606

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New TGA Website - Launches 4 May 2011

<http://www.tga.gov.au/newsroom/media-2022-website-110406.htm>

----- Forwarded by Pamela Carter/TGA/Health on 16/05/2011 12:14 PM -----

From: ADR Reports
To: Pamela Carter/TGA/Health@TTRA
Date: 16/05/2011 11:58 AM
Subject: Fw: Prostheses Metal on Metal hip replacement- ESKA Australia [SEC=UNCLASSIFIED]
Sent by: Yasna Goodwin

Hi Pam
This came through the adr reports email.
Yas

118441

From: [REDACTED]
To: <adr.reports@tga.gov.au>
Date: 16/05/2011 07:06 AM
Subject: Prostheses Metal on Metal hip replacement- ESKA Australia

Dear Sir/Madam

My mother had a hip replacement on the 31/8/09. The orthopaedic surgeon was [REDACTED]
[REDACTED] The prostheses used was a ESKA Metal on Metal prostheses.

[REDACTED] requested a blood test be done for Mums' annual examination, on the 4/10/10, Mums cobalt level was 733 nanamol/litre, it was tested again and on the 18/2/11 the level had risen to 2,004 nanamol/litre. Mum was experiencing pain in her hip, headaches, fluid around the joint and a general feeling of being unwell.

After these high readings [REDACTED] recommended revision surgery which was carried out on the

29/3/11. He said once the metal was replaced with a ceramic ball it would stop the friction caused by metal on metal and stop the cobalt leaching and stop the cobalt level increasing further. He had no information as to what affects the high level of cobalt has done to mums system and vital organs or what it will continue to do, as it could take a long time to get out of her system.

After reading information regarding the re-call world wide of Johnson on Johnson (DePuy) due to the health risks caused by metal on metal prostheses causing cobalt poisoning. I contacted ESKA Australia, they have not taken these prostheses off the market and are still available for surgeons to choose. They were sorry for mums ill health and having to undergo major surgery again to remove the metal prostheses, but were not saying that the prostheses was at fault or that any compensation was available. (So as not to wait for the over 12months waiting period for a hip replacement, my parents paid for the original surgery out of their savings).

██████████ told us he had stopped using these prostheses and 1 out of 10 patients had been adversely affected and required revision surgery.

Surely there needs to be an investigation on the use of the metal on metal prostheses, no matter what Company produces them. The metal on metal prostheses appears to be having the same affect on a large number people that undertake this surgery.

If you require further information please contact me on my email or by telephone ██████████

Yours faithfully

██████████

██████████
Contacted ESKA last wk (11/5/11)

████████████████████