Re: Hazard Alert - SMR L2 Metal Back Glenoid [SEC=UNCLASSIFIED]

[redacted] to: [redacted] 13/08/2012 11:20 AM
Cc: [redacted]

HI [redacted]

Can you help us in drafting a web statement for this?

Best regards,

[redacted] Recalls & Advertising Unit I Office of Product Review I Monitoring & Compliance Group I Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 I www.tga.gov.au
T: [redacted] /Recalls@tga.gov.au

TGA Health Safety Regulation [redacted]

[redacted] Hi [redacted] It's a complicated story but the short v... 13/08/2012 09:36:28 AM

From: [redacted]
To:
Cc:

Date: 13/08/2012 09:36 AM
Subject: Re: Hazard Alert - SMR L2 Metal Back Glenoid [SEC=UNCLASSIFIED]

Hi [redacted]

It's a complicated story but the short version is this:

We did not initiate the Hazard Alert - the company did.

The figures are company figures that they used in their Hazard Alert - We assumed that they come from their own post-market surveillance. We the TGA do not have information that differentiates between the L2 and L1 version of the components, and since the company approached us conceding the problem we did not question the figures.

The SMR shoulders have been identified as having higher than expected revision rates by the NJRR. I am referring the NJRR reports and other information to two shoulder surgeons as recommended by the OEWG. So - in spite of this Hazard Alert, this device is still under investigation.

Regards

[redacted]

Director, Biomaterials and Engineering Section
Office of Laboratories and Scientific Services
Therapeutic Goods Administration

✉ : PO Box 100, Woden, ACT 2606, Australia

☎: [redacted]

[redacted] Hi [redacted] 10/08/2012 05:03:42 PM