

From: [REDACTED]
To: [REDACTED]
Subject: RE: BIRMINGHAM HIP Resurfacing Head [SEC=UNCLASSIFIED]
Date: Thursday, 2 February 2017 10:54:01 AM
Attachments: [image001.png](#)

Dear [REDACTED]

I have submitted an internal request to correct the variant range and total number of devices for ARTG 274333 in line with the revised Declaration of Conformity.

The changes may take a few days to appear on the ARTG. My apologies for the oversight.

Kind Regards

[REDACTED]

From: [REDACTED]
Sent: Tuesday, 31 January 2017 11:44 AM
To: Devices
Cc: [REDACTED]
Subject: FW: BIRMINGHAM HIP Resurfacing Head [SEC=UNCLASSIFIED]

Dear Sir/Madam

I refer to my telephone conversation of today with the TGA regarding the error on ARTG Certificate 274333 for the Birmingham Hip Resurfacing Femoral Head. The history of this is as follows:

1. This was a reclassification application for both the BHR Femoral Head (Sub ID: DA-2015-DR-19876-1, ARTG 274333) and BHR Acetabular Cup (DA-2015-02877-1, ARTG 274334). The variant information on ARTG 274333 states Size (mm): 38 to 62mm, whereas it should be 48mm to 62mm.
2. We responded to a s41JA for both of the applications, together – see copy attached, and see specifically paragraph 6 which explains what happened, and the submitted Declaration of Conformity for the femoral heads.
3. It was my belief that the amendment had been carried out but I have not been able to find any confirmation of that. Certainly, that did occur for the Acetabular Cup – see below.

How do we go about having the ARTG Certificate amended to reflect the true situation?

Regards



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[REDACTED] | Regulatory Affairs Co-ordinator | Smith & Nephew Pty Ltd | ANZ
[REDACTED]

[REDACTED]

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From: [REDACTED]
Sent: Friday, 1 April 2016 10:39 AM
To: [REDACTED]
Subject: RE: BIRMINGHAM HIP Resurfacing Acetabular Cup [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your email. I have amended the application and resubmitted it.

Regards

[REDACTED]

From: [REDACTED]
Sent: Friday, 1 April 2016 10:08 AM
To: [REDACTED]
Subject: BIRMINGHAM HIP Resurfacing Acetabular Cup [SEC=UNCLASSIFIED]

Good Morning [REDACTED],

I have pushed back BIRMINGHAM HIP Resurfacing Acetabular Cup DV-2015-DR-03198-1 as I realised the DoC had been updated and the total number of devices changed to 14. Also the variants size will need to change to 54mm to 68mm. Sorry I thought we had fixed this last year !

Thanks

[REDACTED]

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