

From: [REDACTED]
To: [REDACTED]
Subject: RE: Draft ACSMD Essure Paper [SEC=UNCLASSIFIED]
Date: Thursday, 16 July 2015 4:53:15 PM

Hi [REDACTED]

I found the information through the register (cancelled lists). As the listing was such a long time ago all of the records would be in paper. I apologise for not going through how to find the information when the records go way back. I couldn't find any details of changes in the entries so not sure what changes have been made.

The device was first supplied following "Listing" as a Therapeutic Device in 1999 under ARTG entry number 72090. Essure was transitioned to a Medical Device inclusion in September 2007 and was included under ARTG entry number 144330. Due to a change in the manufacturer (Conceptus to Bayer) and sponsor (Device Technologies to Australasian Medical & Scientific) the Essure's ARTG entry changed to 174123.

Hope this helps.

Kind regards

[REDACTED]

[REDACTED]

Director, Device Vigilance and Monitoring Section (DVM)
Medical Devices Branch (MDB)
Therapeutic Goods Administration

PO Box 100
Woden
ACT 2606

[REDACTED]

From: [REDACTED]
Sent: Thursday, 16 July 2015 2:53 PM
To: [REDACTED]
Subject: RE: Draft ACSMD Essure Paper [SEC=UNCLASSIFIED]

Dear [REDACTED]

I have completed the next draft of the Essure paper for ACSMD.

I am having difficulty tracking the history of the device in Australia, including previous Sponsors etc. There appears to have been two previous ARTG entries for the Essure device and 2 previous manufacturers/Sponsors: Sterigenics US LLC and Australasian Medical & Scientific Ltd. Unfortunately I do not have access to the TRIM containers for these previous ARTG entries. Below is the excerpt from the ACSMD paper that I am having difficulty completing.

Do you know where I could access this information?

The first CE Mark Certificate was issued on 9 February 2001 for the Essure model ESS305. The device was approved by the FDA in 2002. The device was first registered on the ARTG in ___ under ARTG number 72090. The Class III Essure System was registered under ARTG number 174123 in July 2010 [1].

The Essure "Female Sterilisation Kit and Plugs" were first registered in Australia under ARTG 72090, manufactured by Sterigenics US LLC. The Essure 305 model was subsequently redeveloped [2] and marketed by Conceptus Inc. In June 2013, Conceptus Inc was acquired by Bayer Healthcare LLC.

Thank you for your help on this,
Warm Regards,

[REDACTED]

[REDACTED]

Medical Officer
Medical Devices Branch

[REDACTED]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [REDACTED]
Sent: Wednesday, 8 July 2015 9:54 AM
To: [REDACTED]
Subject: RE: Draft ACSMD Essure Paper [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thanks for the first draft. I have made a couple of comments and suggestions for some additions.

I have saved it in TRIM so that I could make comments etc from home.

Kind regards

[REDACTED]

[REDACTED]

Director, Device Vigilance and Monitoring Section
Post-market Surveillance Branch
Therapeutic Goods Administration
PO Box 100
Woden
ACT 2606

[REDACTED]

From: [REDACTED]
Sent: Tuesday, 7 July 2015 12:32 PM
To: [REDACTED]
Subject: Draft ACSMD Essure Paper [SEC=UNCLASSIFIED]

Dear [REDACTED]

I have made a first draft of the paper for ACSMD regarding the Essure device.

I have composed some questions at the end, however these are only ideas at this stage. After your feedback, I will amend the paper accordingly.

Warm Regards,

[REDACTED]

[REDACTED]
Medical Officer
Medical Devices Branch

[REDACTED]
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What class is it? Also, please check whether there were previous inclusion and registrations. If memory serves me there are three ARTG numbers, old and current.

Given my comment above can you check if there have been any changes please?