[redacted]

Re: ARTG Cancellation [SEC=UNCLASSIFIED]

[redacted] to: [redacted] 23/09/2011 08:10 AM

Dear [redacted]

There is still a little way to go in what has been a long (and we believe fair) process. We did not feel that we could justify delaying longer.

In situations such as this, the cancellation is affected by excluding the device from the particular ARTG entry. If and when the Adapter stem is cancelled you will be able to supply other femoral stems that fall within the scope of the inclusion in the ARTG.

Yours sincerely

[redacted]
Chief Biomaterials Scientist
Director, Biomaterials and Engineering Section
Office of Laboratories and Scientific Services
Therapeutic Goods Administration
[redacted]

[redacted] [redacted] 22/09/2011 10:57:32 PM

From: [redacted]
To: [redacted]
Date: 22/09/2011 10:57 PM
Subject: ARTG Cancellation

Dear [redacted]

We are naturally disappointed not to have been given the opportunity to look into this matter further, however we respect the decision which has been made. In my letter of the 13th September I advised you that the ARTG code 118441 is being used by our sponsor to market products other than adapter stems. The attached spread sheet identifies these items; we ask that they are not included in the proceedings you will initiate for the removal of the Adapter Stems from the TGA register. As stated it is our understanding that these products fall into the definition described in attachment A section 41GO of letter reference 2011/011177.

Given the proximity to the end of the 20 day period I would appreciate your confirmation of this point by return.

Best Regards

[redacted]

ORTHODYNAMICS

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[attachment "Items numbers still required under ARTG code 118441.xls" deleted by Jorge Garcia/TGA/Health]

[redacted]

Re: Response letter [SEC=UNCLASSIFIED]

[redacted] to: [redacted] 19/09/2011 01:19 PM

Dear [redacted]

I apologise for the delay in replying to you. I have discussed your request with Dr Kelly.

As we stated in our letter, we believe that ESKA Australia and Orthodynamics have already been provided with ample opportunity to make a case for the performance of the implant. Therefore we are not inclined to wait any longer to begin the proceedings to cancel the registration of the implant.

Further, we are of the view that however they may be interpreted, the results of the tests planned cannot outweigh the "real life" results reported by the National Joint Replacement Registry.

We would welcome any submission that you may have about the implant's performance, results of testing and so on, and if these arrive before the cancellation proceedings are finalised we will happily consider them.

Yours sincerely

[redacted]
Chief Biomaterials Scientist
Director, Biomaterials and Engineering Section
Office of Laboratories and Scientific Services
Therapeutic Goods Administration

[redacted]

[redacted] Dear [redacted] 14/09/2011 01:39:40 AM

From: [redacted]
To: [redacted]
Date: 14/09/2011 01:39 AM
Subject: Response letter

Dear [redacted]

Firstly my apologies as I have previously sent you the attached letter from my BlackBerry but with no explanation. The attached letter is in response to a letter from [redacted] dated 30th August ref 2011/011177.

Should you have any questions with respect to my reply I would happy to answer them.

Best Regards

[redacted]

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