**Australian Government**

**Department of Health and Ageing**
**Therapeutic Goods Administration**

[redacted]
ESKA Australia P/L
Suite 32A-B, 2-6 Chaplin Dr
Lane Cove NSW 2066

Dear [redacted]

**Re: TGA Review of orthopaedic implants with Higher than Expected Revision Rates:**

**1- ESKA Adapter (cementless) Femoral Stem Prosthesis**

**2- ESKA Bionik Resurfacing Femoral Head,**
**when used in conjunction with the Bionik Acetabular Component**

I refer you to our letter dated September 29 2010 concerning the revision rates of hip replacements associated with the ESKA Adapter Femoral Stem Prosthesis and the ESKA Bionik Resurfacing Femiral Head when used in combination with the Bionik acetabular component. Our letter was accompanied by a comprehensive National joint Replacement Registry (NJRR) report on both implants.

The revision rates of the implants were considered by the Orthopaedic Expert Working Group which was established by the Medical Device Evaluation Committee to advise the TGA in relation to the observations made in the Reports. The Orthopaedic Expert Working Group was provided the following information:

1- A full NJRR report for the implant. (This is the same report that was provided to ESKA Australia on 29 September 2010).
2- Verbatim copies of the responses provided by ESKA Australia to our request for further information on the revisions for both implants on 29 October 2010.
3- A summary of the information contained in 1 & 2 above prepared by the TGA.

In considering the performance of the Adapter Femoral Stem Prosthesis, the Orthopaedic Expert Working Group noted the following:

- The generally poor quality of the response from ESKA citing the following shortcomings as examples
    - Much of the information provided by ESKA does not relate directly to the Adaptor device.
    - Most of the arguments made in support of the device rely on the elimination of revisions observed by the NJRR as being "not device related" for reason that are not substantiated by objective evidence
    - Insufficient clinical evidence had been provided to counter-balance the experience reported by the NJRR

- The revision at 3 years is 5.4% compared to 2.7% for other total conventional hips. Members expressed concerns over the high revision rates.
- The Adapter stem has exchangeable femoral necks which could be associated with an increased rate of revision. But this design is not unique, and many stems with adjustable necks have much lower revision rates.
- The recorded revisions 23 revisions are not concentrated in a few hospitals. These suggest that the cause of revision is not related to the surgical technique of a few surgeons.
- While only the cementless form of the implant was identified in 2010, the cemented form of the implant is also of concern and this indicates that the revision rates are likely to be related to implant design rather than surgical technique.

As a result, The Orthopaedic Expert Working advised that the ESKA Adapter femoral Stem prosthesis should be withdrawn from the Australian Market.

In considering the performance of the Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component, the Orthopaedic Expert Working Group noted the following:

- That the quality of the response provided by ESKA is generally poor, citing similar examples as before.
- That only 175 Bionik implants had been implanted, but the revision rate is still very high. 6 out of the 9 revisions were for femoral and acetabular components, and 3 revisions were for the acetabular only.
- That the metal-on-metal bearing solution used in this implant is quite different to similar implants in that a high carbon steel is being used instead of the more conventional Cobalt Chrome alloy.
- That in the publications that ESKA provided as evidence of implant performance elsewhere in the world, the revision rates reported appears to be higher – sometimes much higher than the revision rate reported by the NJRR for this implant

The TGA asked the Working group to comment on the observation made in one of the papers supplied by ESKA – neck shaft angles must be greater than 130° - Whether this affects all similar implants and whether this is commonly known in the orthopaedics field. A member confirmed the importance of the neck shaft angle and that this is commonly known. However, in this case the design of the femoral head does not lend itself to ease of use and the stem is noticeable smaller in diameter and therefore more difficult to seat with accurate alignment. This fact in combination with the implants being metal on metal is a cause for concern.

For the reasons outlined above, the Orthopaedic Expert Working Group advised consideration should be given discontinuing the use of is implant combination.

The TGA will now need to consider the recommendations of the Orthopaedic Expert Working group and decide whether these products can remain in the Australian Register of Therapeutic Goods. Please provide a detailed submission explaining the reasons why the product should be allowed to remain in the Australian Market in light of the higher than expected revision rates being experienced. Your submission should include, but not be restricted to, the following:

- Details of any clinical studies that have been performed using the implants, and data from other orthopaedic registries that may contradict the Australian experience – (please provide full reports of the studies and/or copies of published articles).

- An explanation of the higher than expected revision rate observed by the National Joint Replacement Register for the implants.

- A detailed description of design changes or any other actions that may have been undertaken (or are planned) to improve the performance of the products in relation to rate of revision. Please outline how the changes reduce the risk of revision supporting your argument with clinical evidence, if available.
- An outline of the perceived benefits of using the implants over other similar products, and how these benefits compensate for the increased risk of early revision. This should be backed up by clinical studies and/or surgeon testimonials.

I realise that you have already provided this sort of information in your previous response to our request in October. However, I advise you to review your previous response and to take the opportunity to add any other information and arguments in favour of the implant and resubmit.

Do not hesitate to call me to discuss any aspect of this request. **Please provide your response by Monday 14 February 2011.**

Yours sincerely

[redacted]

Chief Biomaterials Scientist
Director, Biomaterials and Engineering Section
Office of Laboratories and Scientific Services

[redacted]

Monday, 17 January 2011