Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

[redacted]
ESKA Australia
Suite 32 A-B 2-6 Chaplin Drive
LANE COVE NSW 2066

Dear [redacted]

Re: TGA Review of orthopaedic implants which have been identified as having higher than expected revision rates:

ESKA Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

I bring to your attention the 2010 Annual Report of the National Joint Replacement Registry of the Australian Orthopaedic Association (The Report). The Report can be downloaded from http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp

The National Joint Replacement Registry of the Australian Orthopaedics Association (The Registry) has developed a three stage process to identify prostheses that have a higher than anticipated revision rate compared to other prostheses of the same type. The process is explained in pages 142-143 of the Report. The implants that have been identified as having a higher than anticipated revision rates are listed in Tables IP1-IP21 (pages 144-160). Further information about the implants appears in Figures IP1-IP12 (pages 144-162). The Registry has also provided a discussion of the revision rates of implants that have been identified for the first time in 2010.

Joint replacement surgery is associated with significant morbidity and a low (but not negligible) mortality. Failure of an implant leading to revision exposes the patient to joint replacement surgery which may have been unnecessary. Therefore revision surgery is considered to be an adverse event. It follows that an implant that is experiencing unusually high rates of revision is also a matter of concern.

The Registry has identified that the rate of revision of the Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component is significantly higher than that of similar implants in the Australian market. For your convenience, I have attached a detailed report from the National Joint Replacement Registry about the implant. Given this evidence of higher than average revision rates for this implant, and the safety implications of revision surgery, please provide the following information:

1- A summary report of the number and types of problems, complaints and adverse events that ESKA Australia and the Manufacturer have received in relation to the implant. The report should be in the form of a table with a count of reports against each type of problem, complaint or adverse event.

2- The number of implants that have been supplied and the number of revisions associated with these implants that have been reported to ESKA Australia. Please provide both Australian figures and world-wide figures.

3- Your own estimate of the revision rate for the implant – (for example: the 5 year revision rate, the 10 year revision rate, or the revision rate in number of revisions per 100 component years) and an explanation of how this revision rate was estimated.

4- Details and results of any clinical trials, clinical studies, or overseas registry information that may be available for the implant

5- An explanation of the higher than average revision rate observed by the Australian National Hip Replacement Register for the implant.

6- A detailed description of design changes or any other actions that may have been undertaken to improve the seemingly poor early performance of the product in relation to early revision. Please outline how the changes reduce the risk of early revision supporting your argument with clinical evidence, if available.

7- An outline of the perceived benefits of using the Bionik Resurfacing Femoral Head over other similar products, and how these benefits compensate for the apparently increased risk of early revision.

8- Any other information about the implant that you wish the TGA to consider in addition to the data from The Registry.

The information that you provide will be reviewed by the Orthopaedic Expert Working Group established by the Medical Device Evaluation Committee (now the Advisory Committee on Medical Devices, ACMD) to advice the TGA. The Working Group will advise ACMD and the TGA whether the revision rate of the product is unacceptable, taking into consideration the reasons for revision and special needs for the product and any other information that you provide. If the information requested is not made available, the Working Group may need to make their recommendation based on the National Joint Replacement Registry data alone. The advice provided by the Working Group will provide a basis for the TGA considering whether any regulatory action is required.

Your response should be provided by Friday 22 October 2010. Please note that the Orthopaedic Expert Working Group will meet soon after, therefore there is very little scope for extension of this deadline. Do not hesitate to call me to discuss any aspect of this request.

Yours sincerely

[redacted]
Chief Biomaterials Scientist
Director, Biomaterials and Engineering
Office of Laboratories and Scientific Services

[redacted]

29 September 2010

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Facsimile

Date:	29 September 2010	**Total pages:**	
TO:	ESKA Australia	**Telephone:**	[redacted]
Attention:	[redacted]	**Facsimile:**	[redacted]
Regarding:	TGA Review of the 2010 NJRR Report		
FROM:	[redacted]	**Telephone:**	[redacted]
Branch/Div.:	Office of Laboratories and Scientific Services	**Facsimile:**	

If you do not receive all pages, please telephone the sender immediately

MESSAGE:

A letter requiring prompt attention follows. A printed copy will follow by mail.