From: [redacted]
To: [redacted]
Subject: s41JA Notice- Smith and Nephew - Birmingham Hip Resurfacing Head and Acetabular Cup [SEC=UNCLASSIFIED]
Date: Tuesday, 8 December 2015 1:30:04 PM
Attachments: s41JA-Smith and Nephew- Birmingham Hip Resurfacing Head and Aceatbular Cup.pdf

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Dear [redacted]

I refer to your applications DV-2014-DR-19876-1 BIRMINGHAM Hip Resurfacing Head and DV-2015-DR-03198-1 BIRMINGHAM HIP Resurfacing Acetabular Cup.

I am writing to request additional information under Section 41JA of the Therapeutic Goods Act 1989. Please note that I require your response by **15 January 2016** to continue with your application. If no response is received regarding this request for information the application will lapse (section 41FK(c) of the Act).

Please find attached the notice under section 41JA of the Act requesting further information.

Please note: Directions on how to respond to the s41JA notice is included in the letter attached. Please do not reply or provide any response to this notice to this email account as it will not be actioned. Please direct all enquiries to devices@tga.gov.au

Regards
[redacted]

[redacted]
Departmental Officer
Devices Application & Verification
Devices Authorisation Branch
Phone: 1 800 141 144
Email: [redacted]

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

Australian Government

Department of Health

Therapeutic Goods Administration

TRIM 2015/008233 and 2015/008236

[redacted]
Smith and Nephew Surgical Pty Ltd
PO Box 393
NORTH RYDE NSW 1670

Email: [redacted]

Attention: [redacted]

Notice under section 41JA of the Therapeutic Goods Act 1989 requiring information/documents to be provided

Application for Inclusion in the ARTG:	Submission ID:	Unique Product Identifier (UPI)
DV-2015-DR-19876-1	DA-2015-02876-1	BIRMINGHAM HIP Resurfacing Femoral Head
DV-2015-DR-03198-1	DA-2015-02877-1	BIRMINGHAM HIP Resurfacing HAP Coated Acetabular Cup

Information is requested by no later than close of business 15 January 2016.

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41JA of the Therapeutic Goods Act 1989 (the Act), I have made a decision to request information in relation to the abovementioned applications for the inclusion of the kind of medical devices BIRMINGHAM HIP Resurfacing Femoral Head and BIRMINGHAM HIP Resurfacing HAP Coated Acetabular Cup in the Australian Register of Therapeutic Goods (ARTG).

I have made this decision because following evaluation of the information provided to the Therapeutic Goods Administration (TGA) in relation to this application, I am not satisfied as to all aspects considered in the application audit.

In particular, I am not satisfied that the information provided to the TGA has demonstrated that all matters in relation to which certifications have been made under section 41FD are correct, including the certification made under:

- Paragraph 41FD(d) of the Act, that the Devices complies with the essential principles;
- Paragraph 41FD(e) of the Act, that you, as the applicant, for the inclusion of the Devices in the ARTG, have available sufficient information to substantiate that compliance with the essential principles or have procedures in place, including a written agreement with the manufacturer of the Devices setting out matters required by the regulation to ensure such information can be obtained from the manufacturer within the period specified in the Regulations; and

– Paragraph 41FD(j) of the Act, that the information included in or with the applications is complete and correct.

Therefore, additional information is required prior to a decision being made whether to include the Devices in the ARTG.

Important
If you fail to comply with this notice and information relating to the Devices is not received by the TGA within a further 10 working days from the day specified in this notice (see the day specified above), applications DV-2015-DR-19876-1 and DV-2015-DR-03198-1 will lapse (subsection 41FK(c) of the Act).

For further information refer to:
- the relevant legislation:
  - *Therapeutic Goods Act 1989* (http://www.comlaw.gov.au/Series/C2004A03952);
  - *Therapeutic Goods (Medical Device) Regulations 2002* (http://www.comlaw.gov.au/Series/F2002B00237/Compilations); and
- Australian regulatory guidelines for medical devices (ARGMD) (https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices- argmd)

Background:
On 28 April 2015, TGA received the applications for inclusion of the Devices in ARTG, and on 21 May 2015 the TGA notified you that your applications were selected for audit and requested further information regarding the medical devices BIRMINGHAM HIP Resurfacing Femoral Head and BIRMINGHAM HIP Resurfacing HAP Coated Acetabular Cup

On 21 July 2015 you provided the following information:
- Sponsor correspondence dated 21 July 2015 including information on the revision rate analysis and Magnetic Resonance Imaging (MRI) Safety.

The information provided has been assessed and I have come to the view that further information is required in order for me to conclude whether the certifications made under section 41FD of the Act are correct.

1. Essential principles
Kinds of medical devices can be included in the ARTG, if amongst other things the device complies with relevant provisions of the essential principles (EP)[1].

Under subsections 41FD(d) and (e) of the Act, you as the applicant for inclusion of the Devices in the ARTG, certified that it complies with essential principles, and that you have available sufficient information to substantiate the compliance of the Devices with the essential principles or have procedures in place to ensure that this information can be obtained from the manufacturer within the period specified in the Regulations.

Magnetic Resonance Imaging (MRI)
The information provided in relation to this application has indicated that the Devices are hip joint replacement components that are Magnetic Resonance (MR) conditional. That is,

[1] The essential principles set out the requirements relating to the safety and performance of medical devices. Section 41CA of the Act prescribes that these requirements are set out in the Regulations. Regulation 2.1 specifies that the essential principles are set out in Schedule 1 of the Regulations. There are six general principles and nine principles about design and construction (some principles may apply to devices on a case[7] by[7] case basis).

under certain conditions a patient with the implant can be safely scanned in the MR environment.

The MR environment may pose risks to patients with implants primarily due to electromagnetic field induced force and torque, radio frequency heating, and the creation of artefacts. Both ferromagnetic and non-ferromagnetic devices of certain geometries may experience heating caused by electromagnetic field interactions.

The TGA assessment of the information you provided to support the MR conditional status of the Devices has now been completed and the clinical assessor has identified the following issue:

- The copies of the labels provided with the applications do not indicate the MRI status of the Devices. EP 13.2 states that the information required to be provided with a medical device, must be provided on the device itself, or if this is not practicable, on the packaging used for the device, on a leaflet, or in a printed document or other media. EP13.3 item 5 requires any warnings, restrictions or precautions that should be taken in relation to use of the device. Therefore to comply with EP 13.2, the appropriate icon relating to the MRI status for the Device should be provided on the label for the Device (in accordance with ASTM 2503-13 which provides for the standard practice for the marking of medical devices and other items for safety in the magnetic resonance environment).

Based on the above, the information provided to the TGA is not sufficient to demonstrate compliance of the Device with the essential principles.

Therefore, you need to provide further information to substantiate compliance of the Device with the essential principles.

INFORMATION TO BE PROVIDED

You are requested therefore, to provide information listed below within the prescribed timeframe:

- Copies of the updated labels that indicate the MR Status of the Device in accordance with ASTM 2503-13; **or**
- Evidence on how the manufacturer intends to demonstrate compliance with EP13.3, item 5 in relation to the MR status of the Devices.

IMPORTANT

Please ensure that all information that has been required is provided. The first response received by the TGA will be considered to be the complete and final response for this submission.

Please do not provide the same information that has already been submitted and evaluated in the previous submissions. It is advisable to be precise in sending the data specifically addressing the concerns identified in this Notice.

Failure to provide sufficient response may result in the Delegate making a decision not to include the device in the ARTG.

If you require further information please refer Section 3 of the Australian Regulatory Guidelines for Medical Devices (ARGMD)
(http:// www.tga.gov.au/sites/default/files/devices-argmd-01.pdf)

All text must be in English, pictures must be clearly labelled, and text and picture must be legible.

These documents should clearly articulate the manufacturer's intended purpose for the Device, and demonstrate compliance with the regulatory requirements, including compliance with the essential principles.

Timeframe for submitting this information
Under Regulation 5.2 the period for obtaining information that demonstrates that the matters certified under section 41FD were correct in relation to the compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device, is 20 working days.

Therefore, consistently with the above, I request that you provide your response to the address specified below by no later than close of business 15 January 2016.

Lapsing or Rejection of the Application
If no reply is received in response to the Notice within a further 10 working days from the day specified in this notice, the application will lapse (section 41FK(c) of the Act).

Failure to provide sufficient response may also result in the Delegate making a decision not to include the device in the ARTG (refer section 41FI(3) of the Act).

You will also have a right of review of any decision not to include the Devices in the ARTG, however, lapsing of the applications is not 'an initial decision' within the meaning of section 60 of the Act.

If the application lapses or is rejected, you may submit another application at a later date, once all the information is available. Application fees and assessment fees will not be refunded once an application is lapsed or rejected.

Withdraw
You may withdraw your application at any time prior to a decision being made whether or not to include the devices in the ARTG. You should note, however, that the fee paid for the application is not refundable (http://www.tga.gov.au/about/fees[7] refunds.htm). If you wish to withdraw your application, you should advise the TGA of this request in writing, via e[7] mail: devices@tga.gov.au

How to present the submission
The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted in support of previous applications that are already included in the ARTG, or still in process, is not acceptable and will not be considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor. All text and pictures must be legible, and pictures must be clearly labelled.

If your submission is less than 15 pages, you may clearly state the application ID and the applicant name in the subject line and email your submission to: devices@tga.gov.au.

If your submission is longer than 15 pages, it should be sent to:
Devices Application and Verification Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

The information should be provided in either of the following formats:

a) An electronic copy (in the form of a CD or DVD continuing all of the relevant material) – [**Preferred Method]**
Note: The electronic copies of information must **not** be sent to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

b) A single hard copy of the information (two-sided print is acceptable).
   - Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.
   - The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
   - The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

Review of the decision
Should you wish to seek a review of my decision to require you to provide information/documents about the Device, your rights of review are outlined in Attachment A to this letter.

Yours sincerely,

[redacted] (Signed electronically)
Delegate of the Secretary for the purposes of section 41JA of the Act
Medical Devices Branch
08 December 2015

Attachment A

Review of the decision
This decision is an 'initial decision' within the meaning of section 60 of the Act.

This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

Senator the Hon. Fiona Nash,
Minister for Rural Health c/- Parliament House
CANBERRA ACT 2600

Your letter should be headed **"Appeal Under Section 60 of the *Therapeutic Goods Act 1989*".**

What you should provide in support of your request for reconsideration
You should include with your request for reconsideration any information that you would like the Minister to consider. Under subsection 60(3A) of the Act, the Minister is not able to consider any information that you provide after the making of the request unless the information is provided in response to a request from the Minister, or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

To facilitate the consideration of your request it is also requested that you:
1. Include a copy of the decision you want reconsidered;
2. Describe with as much specificity as you can, exactly what parts of the decision you believe are incorrect or in relation to which you object, and set out the reasons;
3. Identify the parts of the information you provide in support of the request that relate to each of those reasons; and
4. If the decision does not relate to you or your company, describe how your interests are affected by the decision.

The Minister may either personally deal with the appeal or send it to be dealt with by one of the Minister's delegates within the Department.

If you are dissatisfied with the result of the decision on the reconsideration then, subject to the *Administrative Appeals Tribunal Act 1975*, you may appeal to the Tribunal for review of that decision.

Important: please note that my decision remains in effect unless and until it is revoked by the Minister or one of the Minister's delegates as a result of an internal review under section 60, is set aside, varied, or remitted by the AAT or is otherwise overturned