152

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

File Reference:
Review ID: 20100028

[redacted]
Managing Director
[redacted]

Post Market Review Request for Information under authority of Section 41JA of the *Therapeutic Goods Act 1989*
ARTG Number: 152697

I refer to the electrical impedance scanner with the above Australian Register of Therapeutic Goods (ARTG) number.

Reasons for the request for information

This product has been chosen to undergo a post market review.

Under the authority contained in Section 41JA of the *Therapeutic Goods Act 1989*, you are hereby requested to provide the information detailed below **within 20 working days** from the date of this letter and no later than **22 April 2010.** If you are unable to provide this information within the timeframe please contact the delegate to request an extension.

Please supply the following:

1. MANUFACTURER'S AUSTRALIAN DECLARATION OF CONFORMITY

An original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity, as required under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Notes:

The declaration of conformity must conform to Australian requirements. A European declaration of conformity is not acceptable.

Please refer to *Guidance Document #5 – The Declaration of Conformity* (available at http://www.tga.gov.au/docs/pdf/devguid5.pdf).

2. POST MARKET DATA
   - Reports on adverse events for this device both here and overseas
   - Problem reports for this device both here and overseas
   - Risk Analysis on reported problems
   - Regulatory Action taken by the manufacturer in the past

3. Labels for the device

Address: PO Box 100 Woden ACT 2606 Website: www.tga.gov.au
Telephone: 1800 809 361 Facsimile: 02 6232 8555 ABN 40 939 406 804

4. Instructions for Use

5. Advertising material (it is important to note that any advertising material submitted during this review is not assessed for compliance with the advertising requirements. The advertising material is only used to assist with clarifying the manufacturer's intended purpose for the device).

6. Copies of all certificates from Notified Bodies that support the inclusion of the device on the ARTG

7. The number of devices distributed:
   - in total worldwide, and
   - in total in Australia.

8. Copies of the clinical evidence used to establish conformity with Australian Essential Principle 14, and as described in *Guidance Document Number 4: Clinical Evidence Requirements for Inclusion of Medical Devices in the Australian Register of Therapeutic Goods,* and as required by Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, including evidence to support the clinical competence of its author (eg a short curriculum vitae).

9. Risk Management reports for the product.

10. Electrical safety test reports/ certificates for electromedical equipment.

Please forward this information to –

Administrative Officer
Market Vigilance Monitoring Section
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Or
Administrative Officer
Market Vigilance Monitoring Section
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Please quote the above REVIEW ID number on all correspondence relating to this post market review. This information is essential for the TGA to track and identify all pieces of data relevant to the medical device entry on the ARTG.

Penalties for non-compliance with this request

Failure to comply with a notice issued under Section 41JA of the Act constitutes an offence under section 41JB (3) of the Act with a maximum penalty of 500 penalty points. Failure to comply with this notice might also lead to suspension or cancellation of the kinds of medical devices from the ARTG.

Providing false or misleading information may attract criminal and civil penalties. The criminal penalties are set out in subsections 41JB (4) to 41JB (7) of the Act.

It is a three tiered offence regime:

- Subsection 41JB (4) of the Act attracts a maximum penalty of 5 years imprisonment and/or 4,000 penalty units where a person gives false or misleading information in response to a section 41JA notice, and use of the medical device has resulted in, will result in, or would result in harm or injury to any person;

- Subsection 41JB(5) of the Act is a strict liability offence that attracts a maximum penalty of 2,000 penalty units where a person gives false or misleading information in response to a section 41JA notice, and harm or injury would be likely to occur to any person if that kind of medical device were used; and

- Subsection 41JB (7) of the Act attracts a maximum penalty of 12 months imprisonment and/or 1,000 penalty units where a person gives false or misleading information in purported compliance with a section 41JA notice.

The civil penalties for giving false or misleading information in purported compliance with a notice are set out in section 41JBA of the Act. The maximum penalties under this section are 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

Provisions for appeal against this request for information are attached.

Please contact the undersigned on 62328299 and judy.zilber[redacted] if any aspect of this request for information requires clarification.

Yours sincerely,

Judy Zilber
Delegate of the Secretary
Market Vigilance Monitoring Section
Office of Devices, Blood and Tissues
TGA

23 March 2010

Section 41JA Appeal Provisions

Informal Arrangements

TGA Delegate
If you have concerns with this request for information, you are encouraged to discuss the matter with the TGA prior to lodging an appeal. You should contact Ms Pam Carter, Director, Market Vigilance Monitoring Section, ODBT, TGA, email Pamela.carter[redacted]

Formal Arrangements

Reconsideration by the Minister
The decision to request this information is an "initial decision" within the meaning of *Section 60 of the Act*. This means that if you are a person whose interests are affected by this decision, and you wish to appeal against this decision, you may do so in writing to the Minister under Section 60 of the Act. 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:

Parliamentary Secretary to
the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

The letter should be headed:

"APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989"

In accordance with the Act the Minister may delegate the power to consider an appeal. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may apply to the Administrative Appeals Tribunal for a review of the Minister's/Delegate's decision.

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Telephone: 1800 809 361 Facsimile: 02 6232 8755 ABN 40 939 406 804