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Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

File Reference: 2010/004802
Review ID: 20100028

[redacted]
Managing Director
[redacted]

PROPOSAL TO CANCEL INCLUSION
Notice under Section 41GN(2) of the *Therapeutic Goods Act 1989* informing [redacted] of a proposal to cancel ARTG Number: 152697 – electrical impedance scanner - from the Australian Register of Therapeutic Goods.

As delegate of the Secretary for the purpose of section 41GN(2)of the *Therapeutic Goods Act 1989* (the Act), I am writing to inform you that I am proposing to cancel the inclusion of the above product under section 41GN(1) of the Act.

Information Considered

In making my decision I have taken into consideration the following;

- the information for this device supplied by [redacted] in the full Application for Inclusion into the Australian Register of Therapeutic Goods,
- the Therapeutic Goods Act 1989 (the Act),
- the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations),
- a faxed letter to the TGA from [redacted] dated 20 April 2010,
- email correspondence between [redacted] of [redacted] and the TGA dated 21, 27 and 29 April and 17 May 2010,
- details of a phone conversation between [redacted] and TGA dated 24 April 2010.

Further to the above I make the following comments;

The sponsor of the device has not met the requirements of section 41GN(1) (c) of the Act in that they have not supplied information as requested under s41JA on 23 March 2010 in the timeframe specified.

Statement of Reason for proposing to cancel

I am satisfied that, in accordance with section 41GN(1) (c) of the Act, that [redacted] has failed to provide the information as requested under S41JA of the Act.

The TGA has been in contact with your representative, [redacted] on several occasions and been given assurances information would be forthcoming but to date the TGA has not received any further information

Actions Required

To prevent a Notice of Cancellation you are hereby given the opportunity to make a submission in relation to this proposed cancellation and provide justification as to why the nominated ARTG entryl 52697 should not be cancelled from the ARTG.

Your submission must be received **in 20 (twenty) working days from the date of this notice.** Any submission should be sent to Ms Pam Carter, Director, Market Vigilance Monitoring Section at email pamela.carter[redacted] or postal address;

Ms Pamela Carter
Market Vigilance Monitoring Section
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Proposed Date of Effect

If no submission is received, cancellation of this inclusion will take effect on 25 June 2010.

If you require further assistance or information regarding this matter, please contact Pam Carter, Director, Market Vigilance Monitoring Section of this Office on (02) 6232 8713.

Yours sincerely,

Larry Kelly
Delegate of the Secretary
Head
Office of Devices, Blood & Tissues

18 May 2010