Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

29 July 2011

Dear Committee Secretary,

Re: Inquiry into the Regulatory Standards for the Approval of Medical Devices

Cancer Council WA is an independent not-for-profit organisation that conducts research, cancer prevention and support programs, and advocacy in order to reduce the burden of cancer on the community. We hold grave concerns about certain unproven imaging devices that are commercially promoted as effective cancer detection technologies and viable alternatives to mammographic screening, assertions which are not supported by evidence. The devices use technologies such as Electrical Impedance, Computerised/Mechanical Breast Imaging, Digital Infrared Thermal Imaging and Thermal Radiometry. Cancer Council continues to actively support the activities of the Therapeutic Goods Administration and the Australian Competition and Consumer Commission to ensure that such alternative breast imaging services do not mislead Australian consumers.[1]

We appreciate the opportunity to contribute to the Inquiry into the Regulatory Standards for the Approval of Medical Devices. Although we commend the TGA for its action in cancelling some unproven breast imaging devices from the Australian Register of Therapeutic Goods (ARTG), we contend that more generally, the manner in which medical devices are regulated does not ensure the quality and efficacy of devices available in Australia, particularly those that are classified as 'lower risk'. We acknowledge that a balance between regulation and promoting an effective and sustainable medical technology industry is important. However, it is imperative that strong regulatory standards ensure that medical devices in use in Australia are safe, beneficial and effective, in order to protect Australian health consumers from harm.

We make the comments in this submission with regard to the following Terms of Reference:

(a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;
(d) the processes in place to ensure that approved products continue to meet Australian standards; and
(f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices.

[1] Please refer to the joint media release from ACCC, TGA and Cancer Council Australia, dated June 9, titled 'Beware of unproven breast imaging technologies, say ACCC, Cancer Council and TGA'

Pre-market:

(i) Assessment procedures

The recent cancellation of breast imaging devices from the ARTG for reasons including the sponsors' failure to substantiate compliance with Essential Principles, apply conformity assessment procedures and/or comply with advertising requirements reveals that devices may be allowed onto the ARTG without adequate pre-market assessment.

We submit that all devices should be actively and comprehensively assessed in the pre-market stage for evidence showing their compliance with the Essential Principles and conformity assessment procedures, and supporting any specific claims made about their safety, benefit, quality and efficacy in the detection, treatment or prevention of disease. Sponsors/manufacturers should also make enforceable undertakings during the pre-market process as to the manner in which their devices are to be advertised. It is important that comprehensive assessment of new devices is made in the pre-market stage so that devices that fail to meet standards do not enter the Australian market.

(ii) Device classification

There is a considerable level of risk associated with certain therapeutic devices on the ARTG, notably breast imaging devices promoted to consumers as cancer detection devices. We recommend the TGA calls for device sponsors to comprehensively justify their classifications in the pre-market assessment process, and where appropriate, to show harmony with international classifications. Several devices marketed as breast cancer detection devices remain on the ARTG, classified as low-medium risk (Class IIa) devices.[2] However, Cancer Council WA has found at least one example where internationally, a substantially similar device is classified in a much higher risk category:

The electrical impedance scanner, ARTG Id: 181980 (ARTG Listing: Attachment 1), is classified in Australia as a relatively low-risk Class IIa device. A similar device with the same intended purpose: 'Imager, breast, electrical impedance' is listed by the US Food and Drug Administration as a Class III device (FDA Listing: Attachment 2). Under the FDA classification scheme, Class III devices are associated with a significant level of risk and require considerable pre-market assessment before they may be released to the market. Specifically, the devices are seen to '…support or sustain human life, are of substantial importance in preventing impairment of human health, or … present a potential, unreasonable risk of illness or injury.' We question why a substantially similar device, which is known to be promoted in Australia as a breast cancer detection device, has been given a far lower risk classification under the Australian system.

We recommend that international device classification is actively checked during the pre-market assessment process, to ensure discrepancies like the previous example are avoided. We also submit that the TGA should act to rectify existing discrepancies. The Global Harmonization Task Force recommends internationally harmonious device classification.[3]

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[2] See, for example, the MEM electrical impedance scanner, ARTG Id 181980 and the SureTouch device, ARTG Id 141616

[3] The Global Harmonization Task Force: Principles of Medical Device Classification, June 27, 2006. Accessed at http://www.ghtf.org/documents/sg1/SG1-N15-2006-Classification-FINAL.pdf (July 2011)

Post-market:

(i) Advertising misconduct

We recommend the TGA actively pursues the available sanctions provided by the Therapeutic Goods Act (the Act) with regard to the advertising offences captured in the Therapeutic Goods Act. For example, we encourage the TGA to pursue sanctions in regard to services that, in breach of Section 42DL(g) of the Act, continue to advertise the breast imaging devices the TGA has cancelled from the ARTG.

(ii) Surveillance reviews

We recommend that post-marketing surveillance of devices is enhanced to ensure their safety and efficacy. A long-term system of regular reviews of listed devices' safety and efficacy that considers both the intended and actual uses for therapeutic devices is necessary. There is a clear need for the TGA to scrutinise the devices currently listed on the ARTG to ascertain whether there is an evidence base to support the claims made about the devices and the uses they are put to.

(iii) Adverse event reporting

We urge the government to consider implementing Recommendation 13 of the Report of the Review of Health Technology Assessment in Australia (the Report), namely 'that in order to improve the contribution of post-market surveillance to patient safety, the TGA take[s] steps to increase the rate of reporting of adverse events, including by health service providers and consumers.'

The current system relies on adverse event reporting by device manufacturers and sponsors, who may not be aware of problems with their devices. We support a comprehensive, accessible national system for the reporting of incidents and adverse events related to medical devices to relevant authorities. Currently, there is limited stakeholder access to post-market surveillance reporting systems, which provide vital information for monitoring of the safety and efficacy of devices. Consumers, patients and clinicians are a rich source of information as end-users of therapeutic products, and so should be encouraged to participate in the post-market surveillance process.

Further, regular, public reporting on the nature of adverse events associated with therapeutic devices is essential. We recommend the TGA publically reports on adverse events associated with therapeutic devices, detailing associated TGA action. We submit that such a system would enhance the manner in which the general public is notified of potentially risky devices.

Cancer Council WA thanks the Committee for the opportunity to submit to this Inquiry.

Yours sincerely,

Terry Slevin
Director, Education and Research
Cancer Council WA

Attachment 1 – Electrical impedance scanner for breast imaging, ARTG Listing:

TGA eBS

Public Summary

Summary for ARTG Entry:	181960 Safe Breast Imaging Pty Ltd - Electrical impedance scanner
ARTG entry for	Medical Device Included Class IIa
Sponsor	Safe Breast Imaging Pty Ltd
Postal Address	PO Box 205, NORTH PERTH, WA, 6906 Australia
ARTG Start Date	8/04/2011
Product type:	Medical Device - Class IIa - Included
Status:	Active
Approval area:	Medical Devices

Conditions

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Devices, Blood and Tissues, Therapeutic Goods Administration following inclusion of the device in the ARTG. (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Manufacturers

Name	Address
SIM-technika	2/Office 908 Chkalova, Yaroslavl, 150054 Russia

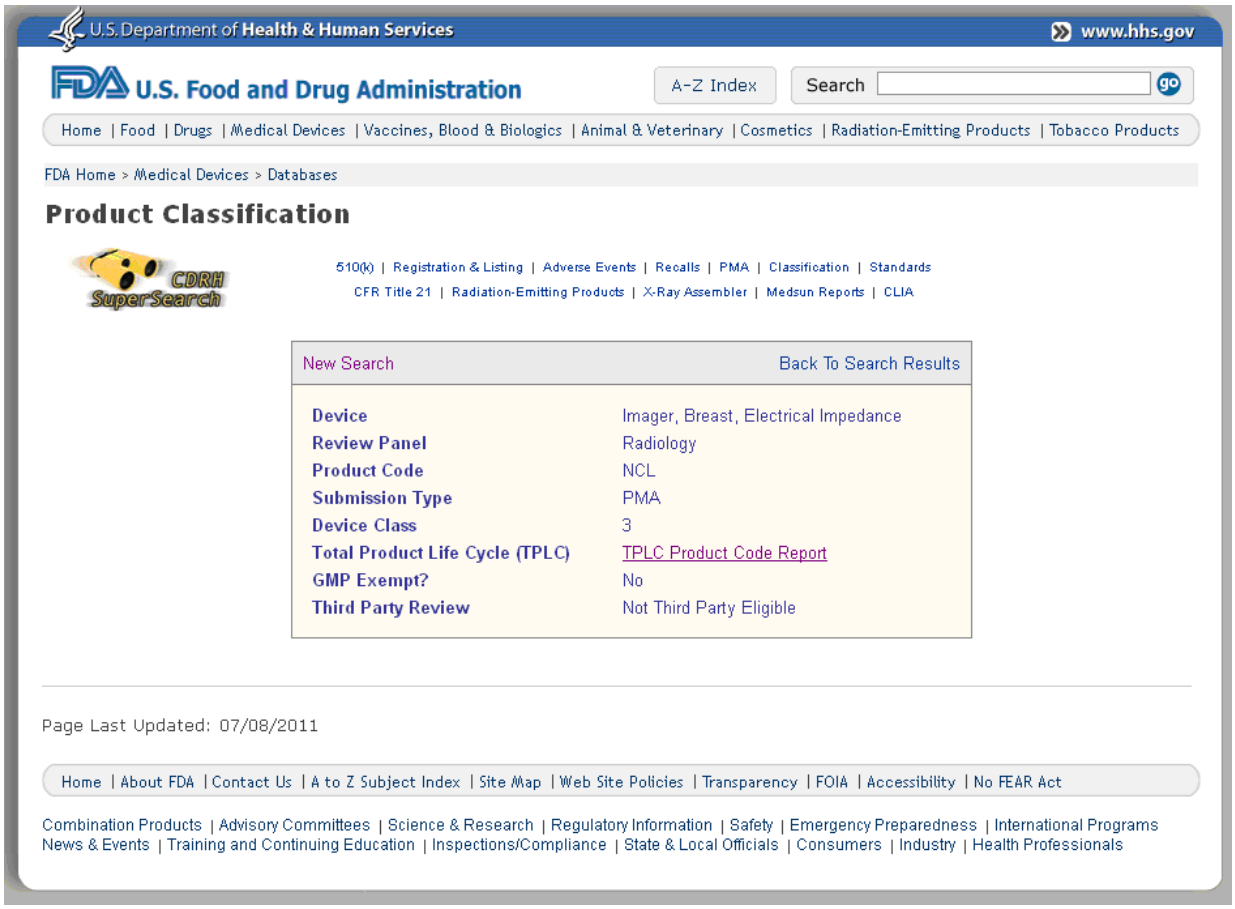
Products

1. Electrical impedance scanner

Product Type	Single Device Product	**Effective date**	8/04/2011
GMDN	42183 Electrical impedance scanner		
Intended purpose	The MEM electrical impedance scanner (EIS), is a real time, three-dimensional, multi-frequency imaging device. It is used to detect, record, and map the differences in capacitance and resistance between neoplastic and surrounding normal tissue. The MEM is designed to be used to record and map the differences in breast tissue. The MEM is a mobile design. It plugs in by USB to a computer or laptop. It does not have its own power source. The MEM electrical impedance scanner is used to map local distributions of tissue electrical impedance at a frequency of 50 Hz by applying a very low voltage electrical signal via a reference electrode on the body, and detecting the resulting impedance values through a sensor array incorporated in a configuration of 256 electrodes. Typically considered an adjunct to other imaging modalities such as mammogram, ultrasound.		

Public Summary

Attachment 2 – Electrical Impedance Scanner for breast imaging, FDA Listing:



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Product Classification

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

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Device	Imager, Breast, Electrical Impedance
Review Panel	Radiology
Product Code	NCL
Submission Type	PMA
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Third Party Review	Not Third Party Eligible

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