



Note for File

This form should be used to record details of meetings (where there are no formal minutes), discussions, telephone conversations or other event that may be part of the decision making process; and completed & saved electronically, printed and placed on the relevant corporate file. Dot points may be used where appropriate.

☒ **Monitoring** – PMR Post Market Product Review ☐ **Vigilance** – IRIS Incident Report & Investigation Scheme ☐ **Other**

File Number (File, DIR or PMR): 2010/004802 Date prepared: 24 Apr 2010

Issue/Title/Product: Review breast imaging product ARTG 152697

Call from [REDACTED] – consultant hired by the sponsor to review all information etc with this particular device. He stated that under new management the sponsor has realised that the conditions of inclusion of the device on the ARTG cannot be met and so will be removing the device from the ARTG. [REDACTED] to consult with the Board of Directors and then fax the form to TGA requesting removal of the product from ARTG. Will fax MVMS a copy of the form at the same time.

The sponsor is hoping to get an Australian manufacturer to then go ahead and produce the device and then enter the device again on the ARTG.

Follow up:

MVMS to request all information that the sponsor is able to provide about the device even though removing their entry from the ARTG. (Clinical evidence; labelling and advertising including website; IFUs; electrical safety standards)
This information is necessary for TGA to review the type of device and how it works.

Signature:

Thilber

Date:

27/4/10