Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office of Devices, Blood and Tissues
Market Vigilance and Monitoring Section

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):* 2010/012670 Date prepared: 16 Sept 2010

Issue/Title/Product: S41JA request – camera thermographic ARTG 143474

- Email from the sponsor [redacted] re TGA reminder letter to provide information in relation to this device.
- Also received a phone call from [redacted] – a user of the device – on behalf of [redacted] who she stated is 'stuck' in Europe at this time. She stated that [redacted] thought his regulatory affairs consultant had requested an extension in which to provide the information.
- I responded to her that I would email [redacted] about the matter as it is his responsibility as the sponsor.

- I rang [redacted] who is listed as [redacted] contact. He told me [redacted] had originally asked him to deal with the request for information but that he had handed the letter back to [redacted] and was now not sure what his role was to be. [redacted] had contacted him again this week and asked why he hadn't requested an extension for this information. He said he was very busy and would probably not be able to get to it soon.
- I told [redacted] I would be contacting [redacted] again and reminding him of his responsibilities as the sponsor of this device.
- [redacted] also stated that he had provided forms awhile ago (to whom?) to have his details removed as the reg consultant for this sponsor.
- I had sent a further email to [redacted] requesting the information be provided by 1 Oct or that he may wish to invoke his appeal rights.

17/9/10
[redacted] phoned to explain situation with Reg Consultant who he thought was assisting him - but isn't.
Explained to him that he has ultimate responsibility for his product on the Register.
Suggested he may wish to consult another Reg Consult.
Directed him to ARGMD to explain how clinical evid needs to be provided eg. Lit search details.
Said he would forward electrical specs via email or on a disc ASAP.
Explained that TGA requires at least part of the required information by due date and at that stage a further decision may be made on an extension of time JZ.

21/9/10 [redacted] has been forwarded some info from sponsor & will email this to me. He requested link to the Inverging Techn report on breast screening devices JZ.

Signature: signed by J Zilber Date: 16 Sept 2010

22/9/10 [redacted] called. Discussion with US manuf who requested he cancel the product and no longer to be sold in Aust. JZ.