Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

Dr William Pouw
Cosmetic Plastic Surgeon

File Reference: 2012/006348

[redacted]

Dear Dr Pouw,

DEVICE INCIDENT REPORT DIR 25692 - PIP Breast Implant

Thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Medical Device Incident Report investigation (IRIS) Database, where it will be evaluated against any previous incidents with the same or similar devices. A copy of the Device Incident Report (DIR) is attached for your reference.

We have also commenced an investigation into your complaint and contacted the product sponsor requesting details of any similar reports.

This process may take some time, but be assured we will advise you of the final outcome of our investigations. However, should you have any questions or further information, please contact me on [redacted]

Thank you for your support of the Medical Device Incident Report Investigation Scheme.

Yours sincerely

[redacted]

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

20/02/2012

DIR 25692 - PIP Breast Implant

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
09/02/2012

ARTG #:

Brand Name:
PIP Breast Implant

Device Class:

Model #:
IMGHC-TX-H-350

Serial #:
128 & 003

Software Version:

Batch #:

Lot #:
38206 & 34606

Manufacturer:

Sponsor:
Medical Vision Australia Pty Ltd
99 King William Street
KENT TOWN SA 5067

Contact Name:
[redacted]

Phone:
(08) 8132 0300

Reporter:

Confidential: Yes

Date of Implant:
21/05/2008

Date of Explant:

Clinical Event Information:

PIP implant removal & replacement with new implants.

Implants sent to TGA.

Patient Outcome/Consequences:

***** End of DIR 25692 *****

Page 2 of 2