From: [redacted]
To: [redacted]
Subject: TGA Request for Information - DIR 65968 - Monash IVF Group - Response due by COB 26 November 2020 [SEC=OFFICIAL]
Date: Friday, 30 October 2020 1:04:52 PM
Attachments: [D20-3634097] DIR 65968 - Monash IVF - Request for information Letter - Response Due 26 Nov 2020.PDF

Dear [redacted]

To assist in the evaluation and resolution of the Device Incident Report (DIR 65968) you recently submitted to the TGA, please provide the information requested in the attached letter and return it to this office **within 20 working days of the date of this letter,** and no later than COB 26/11/2020.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on [redacted] or email IRIS@health.gov.au.

Yours sincerely,
[redacted]

[redacted]
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

File No: E20-373384
Sent by email

[redacted]
Monash IVF Group
21-31 Goodwood Street
Richmond VIC 3121

Email: [redacted]

Dear [redacted]

DEVICE INCIDENT REPORT DIR 65968
Notice requiring information/documents to be provided under Schedule 3, Part 6A, Clause 6.3 and 6.4 of the Therapeutic Goods (Medical Devices) Regulations 2002

I have made a decision, under Schedule 3, Part 6A, Clauses 6.3 and 6.4 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations), to require you to provide information/documents about the in-house IVD – cell free PGT-A (NI-PTG). I am the delegate of the Secretary of the Department of Health for the purposes of Schedule 3, Part 6A, Clauses 6.3 and 6.4 of the Regulations. The information is required for the purposes of the investigation of the above incident report.

You are requested to provide the information/documents listed below including details of any action you have taken in relation to this matter:

1. Please provide a general description of the device

2. Based upon your submitted report, you first became aware of a significant increase in aneuploidy rates in the NI-PTG tested embryos, when compared to the invasive PTG tested embryos, in June 2020 as a part of your routine surveillance program. Please provide:

    a. a copy of your documented procedures for reporting adverse events

    b. a rationale as to why this adverse event was not reported to the TGA until October 2020

    c. any changes you have made, or intend to make, in relation to your reporting procedures for adverse events

3. Based upon your submitted report, you stated that your post-launch surveillance sample size was 805 when you first became aware of this issue in June 2020. During our phone discussion of 22 October 2020, you advised TGA that the number of patients tested using the NI PGT-A test was in the order of 1300, of which around 60% had returned a positive result for aneuploidy. Please confirm:

    a. when you stopped using the test

    b. how many tests were conducted after June 2020 when you identified the issue

4. Please provide details of your system for reviewing experience gained in the post-production phase for the medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied to the design or production of such devices.

5. Please provide details of the design specifications for the device, including:

    a) any medical device standard that has been applied to the device

    b) the results of the risk analysis carried out

    c) if no medical device standard, or part of it, has been applied to the device, please provide the solutions adopted to ensure that each device complies with applicable provisions of the essential principles.

6. Please provide a copy of the clinical evidence, in relation to the device, required by the clinical evaluation procedures, as described in the Part 8 of Schedule 3 of the Regulations.

7. Please provide a copy of the validation report, including details of the tests or trials conducted prior to launching the device in testing clinics.

The requested information must be provided in **20 working days** from the date of this letter and no later than **26 November 2020.**

Address for sending the requested information

Please submit all documents in electronic format only. The requested information should be sent to [redacted] via:

- Email to: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via:

- post to

    Device Vigilance and MonitoringSection
    Medical Devices Branch
    Therapeutic Goods Administration
    PO Box 100
    Woden ACT 2606

- courier to

    Device Vigilance and Monitoring
    Section Medical Devices Branch
    Therapeutic Goods Administration 136
    Narrabundah Lane
    Symonston ACT 2609

Please contact the undersigned on [redacted] or email: IRIS@health.gov.au if any aspect of this request for information requires clarification.

Yours sincerely

Signed electronically by

[redacted]

Delegate of the Secretary
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration
30 October 2020