Australian Government
Department of Health

Deputy Secretary

Mikaela Meggetto
Coroner's Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK VIC 3006

Investigation into the death of Kevin O'Keefe – Court ref: COR 2017 000602

Dear Ms Meggetto

I am writing to you regarding Coroner Audrey Jamieson's recommendations into the death of Kevin O'Keefe. This letter follows my previous correspondence dated 28 September 2018, where following our internal review I committed to provide an update to the Coroner's recommendations. I regret the time taken to complete our review and therefore providing you with the outcomes.

Our review of the Beamer Electrosurgical Unit CE200 with the Argon Unit Beamer Plus (Beamer System) was considered in association with the *Ballarat Health Services Governance and Risk Management Unit Investigation Report* and Essential Principles for medical devices set out in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).

The focus of our review was to determine whether there may be issues of compliance of the Beamer System and the Conmed Argon Probe with the Essential Principles, pursuant to the Coroner's Recommendation 3. The Essential Principles, as noted in the Coroner's findings, impose a number of different requirements in relation to the design and manufacture of medical devices, and the Device Instructions for Use (IFU).

Outcome of the TGA Review

The TGA review determined the overall design and manufacture of the Devices was compliant with the Essential Principles. The Devices' protective measures and the ability to manually set the power settings in a clinical setting were considered appropriate, noting the power setting and duration of application to the surgical site requires clinical judgement by a treating surgeon, having regard to the patient's clinical presentation.

Essential Principle 13.4 requires that the manufacturer provide information with the Device on any undesirable side effects caused by the Device (item 4) and contra-indications, warnings, restrictions, or precautions that may apply in relation to the use of the Device (item 5). The TGA review determined that the IFU for both the Beamer System and the Conmed Argon Probe did not contain adequate information and warnings on duration and wattage for different anatomic sites and advice about the maximum application time.

Actions taken by the TGA and the Manufacturer

We requested the Manufacturer ensure that the IFU complies with the Essential Principles to reduce the likelihood of similar adverse events occurring in future. The Manufacturer has amended the IFU

and user manual of the Beamer System and Conmed Argon Probe to include the following instructions:

I. To decrease the risk of perforation especially in thin walled organs such as the colon, a 'painting' cautery technique should be avoided.

II. For low penetration depth a short application time is recommended and for high penetration depth a long application time should be used.

III. Parameter settings for gas flow and output power are depending on the selected applicator. Please follow the corresponding instructions for use for the applicator.

Further to this, the Manufacturer has amended the Conmed Argon Probe IFU to include suggested wattage ranges for the Side Fire probe type. The inclusion of the suggested wattage range for the Side Fire probe type provides surgeons with information needed to allow for the selection of an appropriate wattage.

The TGA has undertaken a recall action, known as a Product Defect Correction, to alert hospitals and clinicians of the updated warnings in the IFU (recall ID RC-2020-RN-00700-1).

I trust that the above is of assistance to the Coroner. If there are any further queries, please contact ***Mr Simon Waters, Director, Devices Post Market Monitoring Section*** on ***(02) 6289 2368 or simon.waters@health.gov.au.***

Yours sincerely

Adj. Professor John Skerritt

Deputy Secretary

Health Products Regulation Group

24 September 2020