Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Reid Healthcare Pty Ltd

for approval to supply

Reid Healthcare Pty Ltd - The PleuraFlow System - Drain, thoracic

ARTG Identifier	218317
ARTG Start date	10/12/2013
Product Category	Medical Device Included Class IIa
GMDN	11308
GMDN Term	Drain, thoracic
Intended Purpose	The PleuraFlow System is indicated for use during cardiothoracic surgery and chest trauma to proactively remove clots from inside the chest tube to prevent or minimize chest tube occlusion with clot and reduce retained blood.

Manufacturer Details	Address	Certificate number(s)
ClearFlow Inc	1630 S Sunkist Street Suite E Anaheim, CA, 92806 United States Of America	DV-2013-MC-19705-1

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.
- Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the

medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products Covered by This Entry

1. The PleuraFlow System - Drain, thoracic

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 218317
ARTG Start Date: 10/12/2013

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Reference: 2016/008902
R16/359707

Five Corners Pty Ltd
Agent for Reid Healthcare Pty Ltd
13/76 Reserve Road
ARTARMON NSW 2064

Email: brad@fivecorners.com.au

Attention: Brad Sheehan

Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG inclusions for medical devices

ARTG	GMDN code	Classification
218317	[11308] Drain, thoracic	Class IIa

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3D) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or performance of the kind of medical devices for the purposes for which these devices are intended to be used.

I have amended the ARTG entry referenced above, as I am satisfied that the sufficient evidence of the application of the appropriate conformity assessment procedures to the kinds of medical devices has been provided to the TGA.

Therefore, I have varied the following information:

- Name and site address of the Manufacturer

  To: ClearFlow Inc at 1630 S Sunkist Street Suite E Anaheim CA 92806 United States Of America
- Intended purpose

  To: The PleuraFlow System is indicated for use during cardiothoracic surgery and chest trauma to proactively remove clots from inside the chest tube to prevent or minimize chest tube occlusion with clot and reduce retained blood.

Date of amendment: 17 May 2016

For further information on the legislation relevant to these decisions refer:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2015C00471);
- *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Details/F2016C00150).

The ARTG certificate may be downloaded and printed by logging into the TGA Business Services (TBS) website with your user account (for more information refer http://www.tga.gov.au/tga-business-services).

The TGA will not be issuing a hard-copy of the certificate.

Sponsors' ongoing regulatory responsibilities

Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market.

The continued inclusion of the devices of the kind in the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and performance

Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and performance. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

For further information refer the Australian Regulatory Guidelines for Medical Devices (ARGMD) that is available on the TGA website:
http://www.tga.gov.au/industry/devices-argmd.htm

Review of the decision under section 60 of the Act

Should you wish to seek a review of my decision to vary the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Chris Harwood (signed electronically)
Delegate of the Secretary for the purposes of section 9D of the Act
Medical Devices Branch
17 May 2016

Attachment A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.ley@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.