Public Summary

Summary for ARTG Entry: 216653
Emergo Asia Pacific Pty Ltd T/a Emergo Australia - AeroForm™ Tissue Expander System Dosage Controller Kit - Remotely-controlled tissue expander remote control

ARTG entry for
Medical Device Included Class III

Sponsor
Emergo Asia Pacific Pty Ltd T/a Emergo Australia

Postal Address
Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000
Australia

ARTG Start Date
28/10/2013

Product category
Medical Device Class III

Status
Active

Approval area
Medical Devices

Conditions
- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers
Name
Airxpanders Inc

Address
3047 Orchard Parkway
San Jose, CA, 95134
United States Of America

Products

1. AeroForm™ Tissue Expander System Dosage Controller Kit - Remotely-controlled tissue expander remote control

Product Type
Single Device Product

Effective date
28/10/2013

GMDN
59371 Remotely-controlled tissue expander remote control

Functional description
Hand-held remote control contains batteries, antenna & circuitry to provide power to expander. Coded instructions from controller cause programmed release of CO2 resulting in expansion. Controller contains software that tracks dosing activity & volume of expander. Dose is amount of CO2 released within expander each time controller button is pressed. Controller is pre-programmed to limit dosing, but physician can administer doses above programmed patient limits by using Physician Master Key.

Intended purpose
A battery-powered device designed to remotely control expansion of an implanted inflatable tissue expander and intended to be operated intermittently by the patient or physician over a prescribed period to develop tissue coverage prior to the placement of a permanent breast implant. The operator sends a coded instruction by telemetry to release a controlled volume of gas contained in a cylinder within the implant to cause the expansion. It is typically paired with the implant, which contains a programmable identification (ID) chip, in the operating room during implantation. This is a reusable device intended for single-patient use.

Variant Information
Nil variant (as 1 device) Nil

Specific Conditions
No Specific Conditions included on Record

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