RELEASED

Name/Date: MD MS 5/11/2017

REGULATORY STRATEGY FOR AMALGATOME® SD

Exsurco Medical is a registered medical device manufacturer with the FDA and is ISO 13485:2003 certified.

Establishment address:

10804 Green Road
Wakeman, OH 44889

Registration Status:
Status: Active
FEI Number: 3011981870
Date of Registration Status: 2017

FDA Owner/Operator Number:
10053475

The Amalgatome SD is listed with the FDA as a Class I, 510(k) Exempt device.
The product code is GFD.
The regulation number is 878.4820/ Surgical instrument motors and accessories/attachments.

Proposed Intended Use Statement: The Amalgatome SD is intended to excise soft tissue in varying widths and thickness for skin grafting and debridement.

Proposed Indications for Use Statement: The Amalgatome SD System is designed to excise soft tissue in varying widths and thicknesses for skin grafting and wound debridement. It is indicated for open wounds, including wound site preparation (debridement and sharp debridement), removal of necrotic tissue and eschar, and tissue harvesting (autograft harvesting). The Amalgatome SD is accompanied with a Sterilization tray.

Exsurco's Quality Management System is ISO 13485: 2003 certified for the scope of design, manufacture, and servicing of power-operated excision equipment, instruments and replacement blades.

Certificate No:
FM609546
Expiry Date: 01/06/2018

Notified Body:
BSI

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