10/13/2022

Cox-Uphuff International
David J. Schuessler
Regulatory Affairs
P.O. Box 40288
Santa Barbara, California 93140

Re: K874276
Trade/Device Name: CUI, Versafil™, Ste™ Tissue Expander
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FZW

Dear David J. Schuessler:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 2, 1987. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code FZW.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Deborah Fellhauer, OHT4: Office of Surgical and Infection Control Devices, 301-796-9570, Deborah.Fellhauer@fda.hhs.gov.

Sincerely,

Deborah A. Fellhauer -S
Deborah A. Fellhauer -S
2022.10.13 13:14:50 -04'00'

Deborah A. Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

DEC - 2 1987

Mr. David J. Schuessler
Regulatory Affairs
Cox-Uphoff International
P.O. Box 40288
Santa Barbara, California 93140

Re: K874276
CUI Tissue Expander

Regulatory Class: None
Dated: November 5, 1987
Received: November 9, 1987

Dear Mr. Schuessler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson

Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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