



October 27, 2022

David F. Trungale  
16720 Rosewood Ct.  
Brookfield, Wisconsin 53005

Re: K904389  
Trade/Device Name: Si-Pro  
Regulation Number: 21 CFR 878.4014  
Regulation Name: Nonresorbable Gauze/Sponge For External Use  
Regulatory Class: Class I  
Product Code: EYF

Dear David F. Trungale:

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 17, 1990. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 878.4014.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, [Julie.Morabito@fda.hhs.gov](mailto:Julie.Morabito@fda.hhs.gov).

Sincerely,

**Julie A. Morabito -S**

Julie Morabito, Ph.D.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Reconstructive Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

DEC 17 1990

Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850Re: K904389  
SI-ProMr. David F. Trungale  
16720 Rosewood Ct.  
Brookfield, Wisconsin 53005Regulatory Class: Unclassified  
Dated: September 21, 1990  
Received: September 26, 1990

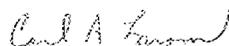
Dear Mr. Trungale:

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 (Pre-market 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 pre-market 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) 427-1116. 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, Ph.D.  
Director,  
Division of Surgical  
and Rehabilitation Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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