



December 15, 2021

Elof Hansson, Inc.
Gay Clarke
25 Van Zant St.
Norwalk, Connecticut 06855

Re: K864529

Trade/Device Name: Laporatomy Sponges Sizes:18x18",12x12",4x18",8x36"

Regulation Number: 21 CFR 878.4450

Regulation Name: Nonabsorbable gauze for internal use

Regulatory Class: Class I

Product Code: GDY

Dear Gay Clarke:

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 16, 1986. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code GDY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Krause, Ph.D., Deputy Office Director, Office of Surgical and Infection Control Devices, 301-796-6970, David.Krause@fda.hhs.gov.

Sincerely,

David Krause -S

David Krause, Ph.D.
Deputy Office Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEC 16 1986

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Ms. Gay Clarke
Sales & Marketing Manager
Elof Hansson, Inc.
25 Van Zant Street
Norwalk, Connecticut 06855

Re: K864529
Laporatomy Sponges, Sizes: 18x18,
12x12, 4x18, 8x36
Dated: November 10, 1986
Received: November 17, 1986

Dear Ms. Clarke:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be 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 your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action 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.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

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