



November 15, 2022

Coloplast, Inc.
Antonio M. Ojeda
Product Director
6206 Benjamin Road
Tampa, Florida 33614

Re: K832908
Trade/Device Name: Comfeel™ Protective Rings
Regulation Number: 21 CFR 878.4014
Regulation Name: Nonresorbable Gauze/Sponge for External Use
Regulatory Class: Class I
Product Code: EYF

Dear Antonio M. Ojeda:

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 12, 1983. 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.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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

Food and Drug Administration
 8757 Georgia Avenue
 Silver Spring, MD 20910

MEMO

Mr. Antonio M. Ojeda
 Product Director
 Coloplast, Inc.
 6206 Benjamin Road
 Tampa, Florida 33614

Ref: K832908
 Comfeel Protective
 Rings

Dear Mr. Ojeda:

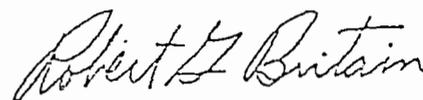
We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market 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 in either class II (Standards) or class III (Premarket Approval), it would be subject to additional controls.

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 relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, 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. Also, the Federal Register will notify you of any additional requirements subsequently 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 should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Office of Medical Devices, Division of Compliance Operations (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,



Robert G. Britain
 Associate Director for
 Device Evaluation
 Office of Medical Devices
 National Center for Devices
 and Radiological Health

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