



December 17, 2021

Medspec Corp.
Jacob Bomberg
Vice President
65 E. Palatime #209
Prospect Heights, Illinois 60070

Re: K812711

Trade/Device Name: Sterile Gauze Pads 12ply
Regulation Number: 21 CFR 878.4014
Regulation Name: Nonresorbable gauze/sponge for external use
Regulatory Class: Class I
Product Code: NAB

Dear Jacob Bomberg:

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 November 2, 1981. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code NAB.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

NOV - 2 1981

Mr. Jacob Bomberg
Vice President
Medspec Corporation
65 E. Palatine #209
Prospect Heights, Illinois 60070

Ref: K812711
Sterile Gauze Pads 12 Ply

Dear Mr. Bomberg:

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 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 into 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 practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will 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 Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 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 Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

Robert S. Kennedy

Robert S. Kennedy, Ph.D.
Associate Director
for Device Evaluation
Bureau of Medical Devices