July 11, 2022

Body Therapeutics, Inc.
Andre V. Hagentorn
6317 Wilshire Boulevard #503
Los Angeles, CA 90048

Re: K821836
Trade/Device Name: Pregnancy (W) edge
Regulation Number: 21 CFR§ 890.3490
Regulation Name: Truncal orthosis
Regulatory Class: I
Product Code: QSB

Dear Andre V. Hagentorn:

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 July 30, 1982. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSB.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Monica D. Garcia, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-2791, Monica.Garcia@fda.hhs.gov.

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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

JUL 30 1982

Mr. Andre V. Hagentorn
Body Therapeutics
6317 Wilshire Boulevard #503
Los Angeles, California 90048

Ref: K821836
Pregnancy (W)edge

Dear Mr. Hagentorn:

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,

Robert G. Britain

Robert G. Britain
Acting Associate Director
for Device Evaluation
Bureau of Medical Devices