Cygnus Of South Florida, Inc.
c/o David Friedman, P.A.
Emerald Hills Professional Park
4700P Sheridan Street
Hollywood, Florida 33021

May 17, 2024

Re: K854265
Trade/Device Name: Simulator
Regulation Number: 21 CFR 862.2100
Regulation Name: Calculator/data processing module for clinical use
Regulatory Class: Class I
Product Code: JQP

Dear David Friedman:

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 March 18, 1986. Specifically, FDA is updating this SE because FDA has better categorized your device technology under product code JQP.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Juliane Lessard, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6126, Juliane.Lessard@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery,
General Hospital and Human Factors 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

MAR 18 -

Cygnus of South Florida, Inc.
c/o David Friedman, P. A.
Emerald Hills Professional Park
4700P Sheridan Street
Hollywood, Florida 33021

Re: K854265B
Similator
Dated: February 18, 1986
Received: February 25, 1986

Dear Mr. Friedman:

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 regulation 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 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,

Fernando Villarroel, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and Radiological Health

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