K070254
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APR 19 2007

Traditional 510(k): Device Modification – Horizon SE

Terminology

Horizon SE = Subject of this 510(k). The Horizon SE is a modified device, a system identical to of the Horizon SE Cathlab with the addition of EtCO2 measurement.

Horizon SE = The predicate device. The Horizon SE Cathlab was cleared for marketing by the FDA (K032997)

VitaLogik 5000 = The predicated device for EtCO2 measurement. The VitaLogik 5000 was cleared for marketing by FDA (K052288)

Intended Use of the Horizon SE

The Horizon SE is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.
Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2007

Mennen Medical Ltd.
c/o Mr. Micha Oestereich
Regulatory Affairs
4 Hayarden Street, Yavne, 81228, Israel PO Box 102
Rehovot, 76100, Israel

Re: K070254
Trade Name: Horizon SE Cathlab with etCO2 Option
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: January 6, 2007
Received: January 26, 2007

Dear Mr. Oestereich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K070254

Device Name: Horizon SE

INDICATIONS FOR USE

The Horizon SE is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressures, pulse oximetry, EtCO2, respiration, cardiac output and body temperatures.

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070254