JUN 24 1999

K991775

MENNEN
MEDICAL LTD.

MENNEN MEDICAL LTD.
Kiryat Weizmann Science Park
P.O.B. 102
Rehovot 76100 Israel
Tel: 972-8-938-3030
Fax: 972-8-940-6519

Date: June 23, 1999

Topic: **Special 510(k) - K 991775 – Statement of Summary**
Computerized Catheterization Laboratory

Establishment Name, Registration Number and Address

Name:	Mennen Medical Ltd
Registration Number:	9611022
Operator Number:	9011766
Address:	Kiryat Weizmann Science Park Rehovot 76100 Israel Tel: 972-8-938-3030 Fax: 972-8-940-6519

Contact person: Ken Raichman, Director of Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health Document Control Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD 20850

Attn.: Ms. Marian Kroen

From: Kenneth Raichman
Director of Regulatory Affairs

Product Name

Proprietary: Horizon 9000 WS
Common: Computerized Catheterization Laboratory (Cathlab)
Mennen Medical part number: 960-100-020

FDA Classification

Classification Name: Programmable diagnostic computer
Classification number: 870.1425 (21 CFR)
Classification: Class II
Product code: 74 DXG

Performance Standards

None promulgated

Predicate Devices

Horizon 9000 WS – cleared for market by FDA on January 6, 1995 – K 940415

Date of preparation of Summary

June 10, 1999

Device Description

The HORIZON 9000 WS (Cathlab) is a state-of-the-art computerized laboratory, whose prime function is the acquisition and display of vital-sign data and waveforms in real time during the catheterization process, creating a fully documented case history. The Cathlab is capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressure, pulse oximetry, respiration, cardiac output and body temperature. 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.

The system has a UNIX Sun Solaris 2 (Ultra 5 computer) that utilizes powerful, real-time software to control the system operation and to process the vital patient sign data measurements acquired from the Physiological Front End or entered manually at the keyboard.

The Thermal Array Chart Recorder provides a continuous recording of all monitored vital signs, patient ID, time and date during the procedures. A Laser Printer is provided in addition to the Chart Recorder in the central console. This provides print-outs of textual and graphical

summaries of all patient data and catheterization procedures.

Base Configuration:

- 4 invasive blood pressure channels
- Diagnostic 7 lead ECG
- 1 Thermodilution cardiac output
- 24 channel thermal array chart recorder
- Pulse Oximetry

Horizon 9000 WS Options:

- 12 lead ECG
- SpO2 monitoring
- Non-invasive Blood Pressure
- Full disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- Cardiology Data Base and Inventory

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Special 510(K) application – K 991775 - Device Modification

Computerized Catheterization Laboratory – Horizon 9000 WS

Indications for Use:

The HORIZON 9000 WS (Cathlab) is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressure, pulse oximetry, respiration, cardiac output and body temperature.
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.

Kenneth Raichman

(Signature)

Kenneth Raichman

Director of Regulatory Affairs
Mennen Medical Ltd.

Date: June 23, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1999

Mr. Kenneth Raichman
Mennen Medical Ltd.
Kiryat Weizmann Science Park
P.O. Box 102
Rehovot 76100
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Re: K991775
Horizon 9000WS Computerized Catheterization Laboratory
Regulatory Class: II (two)
Product Code: 74 DXG
Dated: May 6, 1999
Received: May 25, 1999

Dear Mr. Raichman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K991775

Device Name: MENNEN MEDICAL LTD. HORIZON 9000 WS Computerized Catherization Labotatory

Indications For Use:

The HORIZON 9000 WS (Cathlab) is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressure, pulse oximetry, respiration, cardiac output and body temperature.
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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991775