OCT 1 5 2003

Mennen Medical Ltd.,
4 Hayarden Street, Yavne
PO Box 102, Rehovot
76100 Israel

Date: 16 September 2003

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92(c)**
Special 510(k): Device Modification – Horizon 9000WS Cathlab

Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
Address:	4 Hayarden Street, Yavne, 81228, Israel
Postal Address:	PO Box 102, Rehovot, 76100, Israel
Tel: +972-8-9323333	
Fax: +972-8-9328510	
Contact person:	Asher Kassel, Director of Regulatory Affairs

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

Attn.: Document Control Clerk
From: Asher Kassel, Director of Regulatory Affairs

Product Name:
Proprietary: Horizon 9000WS
Common: Cathlab
Mennen Medical Part Number: 960-100-020 (full system)

FDA Classification of Cathlab:

Classification Name:	Programmable diagnostic computer
Classification Number:	21 CFR 870.1425
Classification:	Class II
Product Code:	DXG

Performance Standards: None promulgated

Voluntary Standards:
IEC 60601-1:
General Requirement for Safety for Medical Electrical Systems - part 1, (1988);
Amendment 1 – 1991-11
Amendment 2 – 1995-03

IEC 60601-1-2 (2001):
Medical electrical equipment. General requirements for Safety. Electromagnetic Compatibility Requirements and Tests.

IEC 60602-2-27 (1994):

Medical electrical equipment, Part 2,
Requirements for safety of electrocardiograph monitoring equipment.

IEC 60601-2-30 (1995):
Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment

IEC 60601-2-34 (1994):
Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment

IEC 60601-2-49 (2001):
Particular Requirements for the safety of multifunction patient monitoring equipment

Terminology:
PFE = Patient Front End, and refers to the data acquisition module of the Horizon 9000WS, the predicate device *before* modification
CFE = Cathlab Front End, and refers to the data acquisition module of the Horizon 9000WS *after* modification, the subject of this Special 510(k).

Predicate Device:

- Horizon 9000WS Cathlab with PFE - K940415 and K991775

General Description of the Horizon 9000WS Cathlab

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 Cathlab runs on a UNIX/Sun Solaris* operating system on a SUN® 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 printouts of textual and graphical summaries of all patient data and catheterization procedures.

Base Configuration: Cathlab parameters

- 4 Invasive Blood Pressure channels
- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Thermodilution cardiac output
- Pulse Oximetry (SpO_2)
- 24 channel thermal array chart recorder

Horizon 9000 WS Options:

- Full Disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- Cardiology Data Base and Inventory
- Optomagnetic or CDR drive
- Choice of Console Table – regular, enhanced or compact

Intended Use of the Horizon 9000WS Cathlab:

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.

Summary of the technological characteristics of the CFE of the Horizon 9000WS Cathlab

The following tables summarize data on the **CFE** (modified device) of the Horizon 9000WS Cathlab:

CFE of Horizon 9000WS Cathlab	
Part/Option Number	960-551-010 (CFE)
Dimensions (H x W x D)	24 x 22 x 10 cm (9 x 11 x 4")
Input Circuit Parameters	**CFE**
Chassis Leakage Current	All patient signal inputs fully isolated (<50 μA). Meets or exceeds ANSI standard: "Safe Current Limits for Electromedical Aparatus," (SCLE) Dec, 1978 item 2.1.1.

	CFE
ECG	7 or 12 leads
Frequency Response	Monitor Mode: 0.5 to 40 Hz Diagnostic: 0.05 to 150 Hz, Exercise: 1 to 25 Hz, -3 dB
Input Impedance:	Typical 20 MΩ Minimum greater than: 5 MΩ differential, DC to 10 Hz; 2.5 MΩ differential 10 to 100 Hz. 3 MΩ differential at 10 Hz
Common Mode Rejection:	At least 100 dB at 50/60 Hz Without lead misbalance 86 db with lead misbalance The common mode rejection ratio is in accordance with ANSI/AAMI EC11 [9] Para. 3.2.1+.
Input Dynamic Range:	±5mV p-p at a rate up to 320mV/sec, as per ANSI/AAMI EC13 [8] Para. 3.2.9.1.
Input offset	± 300mV, as per ANSI/AAMI EC13 Para. 3.2.9.1.
Gain:	Manual selection of 250, 500, 1000, 2000, 4000 and 8000 x ECG. Signal impressed across selected lead
Noise:	Less than 30 μ V p-p referenced to input

ECG	CFE
Pacemaker Pulse Rejection:	Reject pulses from: 2.0 mV to 700 mV pulses of 0.2 to 2.0 mSec pulse widths and ≥3.0mV for 0.1mSec pulse width
Defibrillator Protection:	Up to 5 KV. Amplifier Recovery time: < 3 seconds
Lead Fault Sense:	On any ECG electrode
QRS Detection:	0.25 to 5.0 mV, 70-120 msec width
Synchronous Defibrillation Signal:	Pulse Width: 100 ms. Amplitude: 5 Vdc amplitude into 500Ω, short-circuit proof
ECG Analog Output:	1 Volt / mVolt

Heart Rate	**CFE**
Range:	20 t0 350 bpm
Accuracy:	Within 2 bpm.
Response Time:	Less than 7 sec for step change of 60 bpm from a base of 60 bpm
Blood Pressure	
Input Sensitivity:	5 µvolts/volt/mmHg
Transducer Excitation:	5 Volt
Ranges:	-50 to +300 mmHg
Maximum variation during zero:	± 2 mmHg
Zero Accuracy:	± 0.2 mmHg
Zero Drift:	Less than +/- 0.2 mmHg in 24 hours
Transducer Load Impedance:	300 – 600Ω
Linearity:	Better than 1% of full scale
Common Mode Rejection:	80 dB minimum (reference to chassis 50/60Hz)
Frequency Response:	DC to 12 Hz (DC to 40 Hz optional)
Cardiac Output	**CFE**
Range:	0.5 to 20 liter/minute
Frequency Response:	DC to 15 Hz.
Blood Temperature Range:	27 °C to 45°C
Injectate Temperature Range:	0°C to 25°C. (32°F to 77°F)
Accuracy:	Blood Temp ± 0.05°C: Inj. Temp ± 0.2 °C
Linearity:	Better than 1% of full scale

Temperature	**CFE**
Range:	27 °C to 45°C.
Accuracy:	± 0.2°C.
Respiration	**CFE**
Frequency Response:	0.13 to 2.5 Hz., 3 dB bandwidth.
Range:	8 to 150 bpm.
Excitation:	65 kHz
Pulse Oximetry (SpO_2)	**CFE**
Probe Type:	Masimo™ reusable or disposable
Range:	0% to 100%
Pulse Rate Range:	20-250 bpm, below 20 displays zero
Rate Accuracy:	± 3 bpm
SpO2 Accuracy:	Determined by specific sensor: Adult: ±2 digits between 70% and 100% ±3 digits between 50% and 70%. Neonatal: ±3 digits between 70% and 95%
Auxiliary Inputs	**CFE**
Input Voltage:	+/-5 Volt
Frequency Response:	DC to 120 Hz

Non-Invasive Blood Pressure (NIBP)	**CFE**
Method:	Oscillometric
Initial Inflation:	150 mmHg (adult) 120 mmHg (pediatric).
Pressure Accuracy:	Overall ± 3 mmHg, full scale.
Defib. Pulse Protection	5KV as per ANSI/AAMI EC13 (9), clause 3.2.2.2 and per IEC 60601-2-27 (12), clauses 17,101 and 102
Degree of protection against electrical shock	Type CF and BF. ECG, IBP and CO = CF NIBP and SpO_2 = BF
Electrosurgical Interference Suppression	Yes
Displayed Waveforms	**CFE**
ECG	Up to 12 lead
BP	Up to 4, separate or superimposed
Respiration	1
SpO_2	1
Displayed Numeric Parameters	1
Heart Rate	Yes
Respiration Rate	Yes
SpO2	Yes
BP – Systolic, Diastolic, Mean	Yes
Temperature	2

Alarm Indications	No
Display Functions	**CFE**
Change ECG Lead Selection	YES
Display of Arrhythmia Information	YES
Data Review: Trends	YES
Data Review: Tabular	YES
User defined Configuration Setup	YES
User defined Default Settings	YES
Accessories	Compatible with Mennen Medical Envoy patient monitor

Conclusion of technological characteristics:

We consider the Horizon 9000WS Cathlab with the CFE to be substantially equivalent to the Horizon 9000WS Cathlab with the PFE. We submit that any differences between the two modules:

- fall within the scope of a Special 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

Testing

The Cathlab with the CFE has been subject to extensive safety and performance testing in order to ensure that the signals/waveforms sent by the CFE to the Cathlab have the same characteristics as those sent by the PFE to the Cathlab.
Final testing for the whole Cathlab system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Electrical Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies to applicable industry and safety standards.

Indications for Use

There is no change to the **Indications for Use** for the Cathlab with CFE.
Mennen intends to use the CFE of the Cathlab for "acquiring and displaying essential patient data" according to the approved "Indications for Use" in K991775.
The full "Indications for Use" appear on page 9 below.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Mennen Medical Ltd.
c/o Mr. Asher Kassel
Department of Regulatory Affairs
P.O. Box 102
Rehovot 76100
ISRAEL

Re: K032997
Trade Name: Horizon 9000WS
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DXG
Dated: September 24, 2003
Received: September 25, 2003

Dear Mr. Kassel:

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 (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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K032997

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.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032997