DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2005

Mennen Medical Ltd.
c/o Ms. Micha Oestereich
Regulatory Affairs
4 Ha-Yarden Street, Yavne
P.O. Box 102, Rehovot 76100
ISRAEL

Re: K043564
Trade Name: Horizon Angio Cathlab
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: DQK
Dated: December 20, 2005
Received: December 27, 2005

Dear Ms. Oestereich:

This letter corrects our substantially equivalent letter of January 27, 2005 regarding the trade name.

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 (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 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 continue 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) 276-0293. 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,

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

K043564

Food and Drug Administration
Device Modification - Horizon 9000WS Cathlab:
Special 510(k) for Horizon Angio

INDICATIONS FOR USE

The Horizon Angio 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.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043564

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JAN 27 2005

mennenmedical

Partners in Patient Care

Date: December 14, 2004

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

Establishment Name, Registration Number and Address:

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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: Micha Oestereich, Regulatory Affairs

Product Name:

Proprietary:	Horizon Angio
Common:	Horizon Angio
Mennen Medical Part Number:	960-100-410 (115V) 960-100-420 (230V)

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 60601-1-1 (2000)

Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems

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:

Horizon 9000WS Cathlab = The predicate device The Horizon 9000WS Cathlab was approved for marketing by the FDA (K940415 and K991775 and K032997)

Horizon Angio Cathlab = Subject of this Special 510(k). The Horizon Angio is a modified device, a sub-system of the Horizon 9000WS Cathlab

Predicate Device:

- Horizon 9000WS Cathlab (K032997)

General Description of the Horizon 9000WS Cathlab

The Horizon Angio 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 Horizon Angio software includes graphic presentation of the abdominal, cranial and peripheral vascular system, to support reporting of vascular catheterization.

The Sun Blade 150 workstation is a uni-processor system that runs the Cathlab program on a UNIX operating system. The workstation receives the digitized signals from the CFE via the Ethernet hub, displays real-time vital signs, analyzes, processes, and calculates the vital sign data and waveforms, cardiac status in real time during the catheterization process, creating a fully documented case history. The workstation continuously displays the vital signs waveforms and data on the local LCD displays.
The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

A Laser Printer is provided in the system. This provides printouts of textual and graphical summaries of all patient data and catheterization procedures.

Base Configuration: Cathlab parameters

- 2 Invasive Blood Pressure channels
- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO_2)

Horizon Angio Options:

- Full Disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- CDR, DVD or Optomagnetic drive
- Choice of Console Table – regular, enhanced, compact or without consol

Intended Use of the Horizon Angio

The Horizon Angio 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 Horizon Angio

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

	Horizon Angio
Part/Option Number	960-100-410 (115V)
Dimensions (H x W x D)	24 x 22 x 10 cm (9 x 11 x 4")
Input Circuit Parameters	
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.
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. 3.2.11.
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.

	Horizon Angio
ECG	
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
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	
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)

	Horizon Angio
Blood Pressure	
Frequency Response:	DC to 12 Hz (DC to 40 Hz optional)
Temperature	
Range:	27 °C to 45°C.
Accuracy:	± 0.2°C.
Respiration	
Frequency Response:	0.13 to 2.5 Hz., 3 dB bandwidth.
Range:	8 to 150 bpm.
Excitation:	65 kHz
Pulse Oximetry (SpO_2)	
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	
Input Voltage:	+/-5 Volt
Frequency Response:	DC to 120 Hz
Non-Invasive Blood Pressure (NIBP)	
Method:	Oscillometric

	Horizon Angio
Non-Invasive Blood Pressure (NIBP)	
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	
ECG	Up to 12 lead
BP	2 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

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	Horizon Angio
Alarm Indications	No
Display Functions	
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 Angio to be substantially equivalent to the Horizon 9000WS Cathlab. 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

Final testing for the whole Horizon Angio 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 Horizon Angio.
Mennen intends to use the Horizon Angio for "acquiring and displaying essential patient data" according to the approved "Indications for Use" in K032997.
The full "Indications for Use" appear on page 9 below.