DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 7 2003

Viterion TeleHealthcare LLC
c/o Ms. Thuy Nguyen
Manager, Quality Assurance
555 White Plains Road
Tarrytown, NY 10591

Re: K030419
Trade Name: Viterion 100 TeleHealth Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 19, 2003
Received: August 22, 2003

Dear Ms. Nguyen:

This letter corrects our substantially equivalent letter of November 6, 2003, regarding the trade name and company 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (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

1. 510(k) Summary

For Public Disclosure

Date Prepared: February 7, 2003

Submitter:
Viterion TeleHealthcare LLC
555 White Plains Road
Tarrytown, NY 10591
Phone: (914) 333-6600
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Contact Person:
Sean M. Curry
16787 Bernardo Center Drive, Suite A-1
San Diego, CA 92128
Phone: (858) 675-8200
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Proprietary Name: Viterion 100 TeleHealth Monitor

Common Name: Physiological Monitoring System

Classification: Class II

Product Code: 74 MWI, 870.2300

Substantial Equivalence Claimed to:

1. K004050 Panasonic Tele-Homecare System, Matsushita Electric Industrial Co., Ltd.
2. K952979 HANC Network, HealthTech Services Corp

Description/Intended Use:

The Viterion 100 TeleHealth Monitor is a physiological monitoring system. The system collects, accumulates, transmits patient vital signs and other physiological data from a patient who may be remote from the healthcare practitioner to the practitioner, and provides communication between the patient and practitioner.

The physiological monitoring instruments, selected by the healthcare practitioner, operate in conjunction with the Patient Terminal located in the patient's home, a hospital room, nursing home, or other healthcare facility. The Patient Terminal connects to the server via a conventional telephone line or through the Ethernet.

Summary of Technological Characteristics:

The Viterion 100 TeleHealth Monitor system is a software controlled physiological monitoring device for which the healthcare provider is remotely located from the patient. It is a tabletop unit that communicates with the healthcare provider via a server. The built-in interface allows monitoring of the data directly from the selected physiological instruments. It also allows manual entry of other physiological measurements for those instruments that do not directly connect to the system.

3. Indications for Use Statement

510(k) Number: **K030419**
Device Name: **Viterion 100 TeleHealth Monitor**

Indications for Use:

The Viterion100 TeleHealth Monitor is a physiological monitoring system. The system collects, accumulates, transmits patient vital signs and other physiological data from a patient who may be remote from the healthcare practitioner to the practitioner, and provides communication between the patient and practitioner. It can record physiological information such as:

- Blood Pressure/Pulse
- Blood Hemoglobin Oxygen Saturation (SpO_2)
- Body Weight
- Blood Glucose
- Temperature
- Respiratory Peak Flow

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

-Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K030419

Prescription Use _____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)