JUL 19 2004

RTX Healthcare

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92

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Date of summary: 04/15/2004

Common Name: Physiological Transmitter and Receiver
Trade name: RTX3320 Wireless Telehealth Gateway

Classification name: 21 CFR 870.2910 Physiological Signal Transmitter And Receiver.
Classification no: DRG

Predicate Device:
The RTX3320 device is substantially equivalent to the following predicate device:
510(k) number: K023749
Device name: M3810A Philips Telemonitoring System with M3812B TeleStation.
Applicant: Philips Medical Systems

Submission Device Description:
The RTX3320 telemedicine device perform transmission of physiological patient information to and from wireless patient monitors, and a remote data server healthcare facility using standard digital communication technologies and protocols.
The RTX3320, with its build-in modem, transmits data using the public switched telephone network. It is designed not to interfere with the normal use of phones on the same telephone line.
The RTX3320 device is not operated by, or used directly on a patient, and poses no significant risk to the patient or other people within the patient's home.

Intended use and indications for use:
The RTX3320 device is for use by patients at home. It is intended to be used in combination with a variety of patient monitors upon the prescription of a licensed physician or other authorized healthcare provider. RTX3320 serves as the remote communication link between compatible patient monitors, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center, or with the healthcare/wellness provider or other out-of-hospital caregivers.

The purpose is to transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.
RTX3320 is a "black box" device – it is not connected to the patient and not operated by the patient. The installation must be performed by or under supervision of an authorized professional healthcare company.
This device does not measure, interpret or make any decisions on the vital data that it conveys.

Contraindications, precautions and warnings

This device is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data.
Clinical judgement and experience are required to check and interpret the measurements collected and transmitted.
This device is not for use in systems which substitute for medical care.
This device is not intended for patients requiring direct medical supervision or emergency intervention.

Substantial Equivalence Comparison table:

Item		Predicate device	Submission device
1	Intended use / Indication for use	See section 6.	See section 2.
2	Intended users	Home users and healthcare providers.	Home users and healthcare providers.
3	Site of use	Typically for use in patient's home, placed on a normal table.	Typically for use in patient's home, placed on a normal table.
4	Prescription	The device is intended to be used upon prescription of a licensed physician or authorized healthcare provider.	The device is intended to be used upon prescription of a licensed physician or authorized healthcare provider.
5	System description	Telemedicine system consisting of a device that is working as hub/gateway sending data measured by the system patient monitors to a system data server.	Telemedicine device that is working as hub/gateway sending measured data from compatible patient monitors to a compatible data server.
6	Wireless patient monitors	Wireless connection between the patient monitors and the hub/gateway.	Wireless connection between the patient monitors and the hub/gateway.
7	Transmission	Residential telephone lines	Residential telephone lines
8	Patient Interactions	Display and push buttons for collection of patient typed data	No patient interaction. ("Black box")
9	Measurements taken	Blood pressure, weight, ECG and Blood glucose	Blood pressure, weight, ECG, Blood glucose and other measurements provided from compatible monitor devices.
10a	Contra indications and warnings	The device does not send any real time alarms.	The device is not for emergency calls, and may not be used to send any real-time alarms or time-critical data.

10b	Contra indications and warnings	Clinical judgment and experience are required to check and interpret the information delivered.	Clinical judgment and experience are required to check and interpret the measurements that are taken, collected, and delivered by systems using a RTX3320 device.
10c	Contra indications and warnings	The device is not intended as a substitute for medical care.	The device is not for use in systems which substitute for medical care.
10d	Contra indications and warnings	The device is not for use in systems set up for patients who need direct medical supervision	The device is not for use in systems set up for patients who need direct medical supervision or who might need emergency intervention.
11	Wireless link between patient monitors and the gateway	Short range radio system.	Short range radio system using Bluetooth technology.
12	Environmental specifications	Proprietary information	See section 5.
11	Wireless link between patient monitors and the gateway	Short range radio system.	Short range radio system using Bluetooth technology.
12	Environmental specifications	Proprietary information	See section 5.

Discussion on differences:

Item 1: The intended use / Indications for use for the predicate device and submission device is generally the same. The exact use is for both devices to be decided and supervised by a licensed physician or an authorized healthcare provider, but limited to be within the intended use and with respect to the contra indications and warnings which are also generally the same for both devices.

Item 5 The predicate device is a system consisting of patient monitor devices, a hub/gateway device and a system server software. The Submission device is a hub/gateway device with a specified generic protocol interface to any compatible patient monitor, and with a specified generic protocol interface to any compatible system server. The protocols are validated against existing compatible patient monitors and servers, and in the labeling it is stated that only compatible and system validated patient monitors and servers must be used with the hub/gateway.

Verification and validation done on the compatible patient monitors ensure that no extra safety or performance risks are added when using the submission device compared with the predicate device.

The server side and database management must always be validated by the responsible system operator or provider, and using the generic and properly documented protocol adds no extra safety or performance risks to a system using the submission device compared to the predicate device.

It is very important to state that both the predicate and the submission device may only be used if clinical judgment and experience is used to check and interpret the measurements that are taken, collected and transmitted by the devices.
Item 8: The predicate device is fitted with a display and some push buttons for patient interaction. The purpose is to collect some additional information from the patient. The submission device is not fitted with a display, and no user interaction is possible or necessary to perform the intended use.
The submission device collects the same physiological parameters as the predicate device without necessary user interaction on the device. If additional information is needed this may be achieved by a normal voice phone call.
Item 9: For the predicate device the measurements taken are defined by the patient monitors that are a part of the system. For the submission device the measurements taken are defined by the specific compatible patient monitors. Because of the similar intended use and indication for use for both the predicate device and the submission device, the measurements will typically be the same.
Item 11: Detailed technical specifications about the wireless link between the patient monitors and the Gateway for the predicate device are proprietary and not available for RTX Healthcare. Based on the knowledge available as a leading company within wireless connectivity RTX Healthcare has evaluated that many different short range radio solutions are suitable for this type of devices without adding any additional risks to the patient. RTX Healthcare has chosen the Bluetooth wireless technology used in other medical devices like the Nonin Pulseoximeter (FDA-K041156) developed by RTX Healthcare. The general radio signal safety requirements and FCC Part 15 rules are regulatory requirements that are equal for both the predicate device and the submission device. Since the only purpose using a wireless radio link is to replace a cable, the wireless link in the submission device is evaluated not to add any additional risks within the intended use compared to the predicate device.
Item 12: Detailed environmental specifications for the predicate device are proprietary and not available for RTX Healthcare. This is evaluated not to add any additional risks to the patient since both the predicate device and the submission device, according to the intended use, are designed for use by patients at home. The environmental specifications for the submission device are defined according to IEC60601-1 and specifications available for other medical devices for home use.

Performance data:
The RTX3200 device has been tested to meet the requirements of the following standards and regulations used as acceptance criteria:
IEC 60601-1, IEC 60601-1-2, FCC part 15 and FCC Part 68.
Risk management is performed according to ISO14971:2000.
Based on the fact that the performance comparison of the predicate device and the submission device show that the differences are minor and causes no harm to the user, and the fact that the intended use and indication for use is the same, it was early in the project decided to focus on verification and internal validation instead of large scale validation in form of clinical investigation.
Verification and validation testing activities is conducted to establish performance and reliability characteristics of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUL 19 2004

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THE NETHERLANDS

Re: K041816
Trade Name: RTX3320 Wireless Telehealth Gateway
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: July 2, 2004
Received: July 6, 2004

Dear Dr. van Vugt:

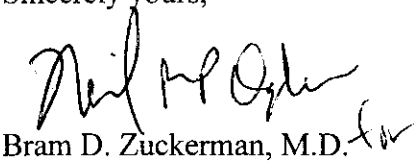
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041816

3. **Indications for use statement**

Indication for Use Statement

510(k) Number (if known):

Device name: RTX3320 Wireless Telehealth Gateway

Indications for Use:
The RTX3320 device is for use by patients at home. It is intended to be used in combination with a variety of patient monitors upon the prescription of a licensed physician or other authorized healthcare provider. RTX3320 serves as the remote communication link between compatible patient monitors, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center, or with the healthcare/wellness provider or other out-of-hospital caregivers.
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This device is not intended for patients requiring direct medical supervision or emergency intervention.

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)

Neil R P Ogden for DDZ
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041816