K050778

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APR 13 2005

510(k) SUMMARY

510(k) Premarket Notification for ScottCare TeleRehab™ 2004 Cardiopulmonary Rehabilitation System (TeleRehab™ 2004)

Submitter's Name, Address, Telephone Number:
ScottCare Corporation
4791 West 150th Street
Cleveland, Ohio 44135
Phone: (216) 362-0550
Facsimile: (216) 267-6129

Contact Person:
Wayne Stripe
Manager of Quality Assurance
ScottCare Corporation

Date Prepared: February 8, 2005

Name of Device:
ScottCare TeleRehab™ 2004 Cardiopulmonary Rehabilitation System (TeleRehab™ 2004)

Name/Address of Sponsor:
ScottCare Corporation
4791 West 150th Street
Cleveland, Ohio 44135
Phone: (216) 362-0550
Facsimile: (216) 267-6129

Common or Usual Name:
Cardiopulmonary Rehabilitation Telemetry Monitoring System

Classification Name:
Radiofrequency Physiological Signal Transmitter and Receiver

Predicate Devices:
ScottCare Corporation's "ScottCare TeleRehab™ System for Cardiac Rehabilitation." (K895719) and Quinton "Q-Tel Rehabilitation Management System." (K041607)

Intended Use:
This device is intended to acquire and condition the ECG signal from a patient so that it can be transmitted via radio frequency (WMTF) with a Stickman telemetry transmitter to a workstation in a hospital or clinical setting where the ECG is displayed and analyzed. This device is for use with ambulatory adult patients, which need monitoring while undergoing cardiac or pulmonary rehabilitation. The data output from monitoring is viewed and stored on a workstation for

tracking of the patients' progress through rehabilitation. Patient demographics, exercise protocol and medical information can be entered via a variety of commercially available wireless input devices or automatically through an HL-7 hospital network interface. A database can be created for use with an Outcomes program.

Technological Characteristics:

Both the TeleRehab™ 2004 and its' TeleRehab predicate are electrically powered, prescription devices with the same intended function and use. Both incorporate the same operational principles; have the same basic performance characteristics, are used in a clinical or hospital environment, and utilize the same basic PC technology on the same ambulatory adult population. Both devices display ECG waveforms of the transmitted signals and include a central monitoring station, one or several workstation computers, a signal transmitter and a receiver. Both devices allow use of multiple receivers and connection to a local area network. Additionally, both devices can be used to develop, edit and produce reports of patient data acquired during the rehabilitation process. Both devices do not require sterilization. Mechanical safety, aside from stability, is not applicable for either device. Stability, electromechanical compatibility, electrical safety and thermal safety testing of the proposed device was performed in accordance with applicable sections of IEC 60601-1 and IEC 60601-1-2 Medical Equipment – Part 1: General Requirements For Safety. Chemical safety is not applicable for either device. Both devices are used in identical anatomical sites. Human factors for both devices are similar and generated data is identical. Ionizing energy is not emitted by either device. The primary difference between the TeleRehab™ 2004 and its' predicate is that the TeleRehab™ 2004 includes a new digital receiver for signal reception. None of the differences between the TeleRehab™ 2004 and the predicate TeleRehab device have an impact on the safety and efficacy of the proposed device. While the Quinton device has additional indications for use which are beyond the TeleRehab™ 2004, they share the same indications for use as when viewed as a Radiofrequency Physiological Signal Transmitter and Receiver pursuant to 21 CFR Part 870.2910. Both the TeleRehab™ 2004 and Q-Tel RMS predicate are electrically powered, prescription devices with the same intended function and use of monitoring and recording ECG data and conditioning the ECG signal so that it can be transmitted by radio waves to a workstation. They incorporate the same basic operational principles, have the same basic performance characteristics, are used in a clinical or hospital environment, and utilize the same basic PC technology on the same ambulatory adult population. Both devices display ECG waveforms of the transmitted signals and include a central monitoring station, one or several workstation computers, a signal transmitter and a receiver. Both devices allow use of multiple receivers and connection to a local area network. Optional workstations may be connected to both systems via network for entering and viewing patient demographic and rehab session data. Additionally, both devices can be used to develop, edit and produce reports of patient data acquired during the rehabilitation process. Both devices do not require sterilization, and utilize a biocompatible medical grade electrode and patient lead that come into contact with the patient. Mechanical safety, aside from stability, is not applicable for either device. Stability, electromechanical compatibility, electrical safety and thermal safety testing of the proposed and predicate Q-Tel device was performed in accordance with applicable sections of IEC 60601-1 and IEC 60601-1-2 Medical Equipment – Part 1: General Requirements For Safety. Chemical safety is not applicable for either device. Both devices are used in

identical anatomical sites. Human factors for both devices are similar and generated data is identical. Either device does not emit ionizing energy.

The primary difference between the TeleRehab™ 2004 and the Quinton Q-Tel RMS device is that the Quinton device includes additional and optional ECG features for other than the intended use for TeleRehab™ 2004. None of the differences between the TeleRehab™ 2004 and the predicate Quinton Q-Tel RMS have an impact on the safety and efficacy of the device when used as the TeleRehab™ 2004 is intended.

Device Description:
ScottCare TeleRehab™ 2004 Cardiopulmonary Monitoring System is an electrically powered device intended for non-diagnostic use in a remote or in-hospital (outpatient) environment. It is used to acquire and condition the ECG signal so that it can be transmitted via radio frequency to a workstation. The telemetry capable system measures the electrical activity of the heart of ambulatory adults undergoing prescribed monitored cardiac or pulmonary rehabilitation, or other patients requiring non-diagnostic monitoring such as Congestive Heart Failure (CHF) patients.

Performance Data:
The ScottCare TeleRehab™ 2004 Cardiopulmonary Monitoring System was tested to and meets the requirements of the following standards.

- IEC 60601-1 Safety of Medical Electrical Equipment Part 1: General Requirements
- IEC 60601-1-2:2004/EN61000-4 Generic Emissions Standard
- EN 55011 Class B Product Specific Emissions
- EN61000-4-2 Electrostatic Discharge
- EN61000-4-3 Radiated Susceptibility
- EN61000-4-4 Electrical Fast Transient Burst
- EN61000-4-5 Surge
- EN61000-4-6 Conducted Susceptibility
- EN61000-4-8 Magnetics
- EN61000-3-2 Harmonic Current
- EN61000-3-3 Voltage Fluctuations and Flicker
- ANSI/AAMI EC-13 Cardiac Monitors, heart meters and alarms (applicable parts only)

Substantial Equivalence:
The performance data shows that ScottCare TeleRehab™ 2004 Cardiopulmonary Monitoring System is substantially equivalent to the ScottCare TeleRehab System for Cardiac Rehabilitation (K895719) and the Quinton Q-Tel Rehabilitation management system (K041607) and is safe for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

ScottCare Corporation
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49458

Re: K050778
Trade Name: ScottCare TeleRehab™ 2004 Cardiopulmonary Rehabilitation System (TeleRehab™ 2004)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: Undated
Received: March 28, 2005

Dear Mr. Devine:

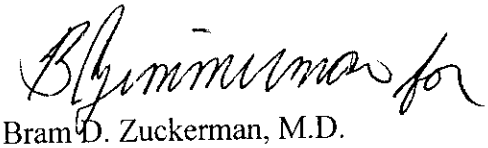
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 may be obtained 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

K050778

Indications for Use

510(k) Number (if known): TBD

Device Name: ScottCare TeleRehab™ 2004 Cardiopulmonary Rehabilitation System (TeleRehab™ 2004)

Indications For Use: This device is intended to acquire and condition the ECG signal from a patient so that it can be transmitted via radio frequency (WMTF) with a Stickman telemetry transmitter to a workstation in a hospital or clinical setting where the ECG is displayed and analyzed. This device is for use with ambulatory adult patients, which need monitoring while undergoing cardiac or pulmonary rehabilitation. The data output from monitoring is viewed and stored on a workstation for tracking of the patients' progress through rehabilitation or other monitoring. Patient demographics, exercise protocol and medical information can be entered via a variety of commercially available wireless input devices or automatically through an HL-7 hospital network interface. A database can be created for use with an Outcomes program.

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

(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 K050778