K082630

Section 6: 510(k) Summary

APR 23 2009

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Telovital's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the **clue medical** and **clue medical BASIC** is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

Sponsor / Manufacturer:	Telovital GmbH Telemedizin Office Park I / Top 4 A-1300 – Vienna – Airport Austria
Contact:	Cherita James M Squared Associates 901 King St. Suite 200 Alexandria, VA 22314 Ph: 703-562-9800 x257 Fax: 703-562-9797 Email: CJames@MSquaredAssociates.com
Date Prepared:	December 8, 2008
Proposed Class:	II
Proprietary Name:	**clue medical** and **clue medical BASIC**
Common Name:	Electrocardiograph
Classification Name:	Electrocardiograph
Regulation Number:	21 CFR 870.2340, 21 CFR 870.2920
Product Codes:	DPS, DXH

Predicate Device:

	Device Name	Procode	Common Name	Class
K082013	clue medical and clue medical BASIC	DPS, DXH	Electrocardiograph	Class II

Indication for Use

The **clue medical** and **clue medical BASIC** are handheld, battery operated single channel electrocardiographs intended for recording and transmitting ECG data by patients who are concerned about their heart rhythm. The **clue medical** and **clue medical BASIC** allow the patient to record their ECG data into the device memory and transmit it for display by healthcare professionals.

Specifically, the **clue medical** and **clue medical BASIC** are intended for patients that are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:

Skipped beats

Pounding heart (palpitations)

History of arrhythmia

The **clue medical** and **clue medical BASIC** ECG data is intended to be used by a licensed health care practitioner. These measurements are not intended for any specific clinical diagnosis. The clinical significance must be determined by the physician.

Device Description

The **clue medical** is an handheld battery operated single-channel ECG recorder featuring four fixed electrodes on the back of the device, an ECG lead connector, an IrDA and a Bluetooth interface and one single button to record and store up to ten ECG recordings with 30 seconds or two minutes duration. The stored ECG tests are processed into a printable Portable Document Format (PDF) that can be transmitted two ways. The PDF can be transmitted via IrDA or Bluetooth to an IrDa or Bluetooth capable local PC or printer. If the receiving device is not IrDa or Bluetooth capable, an optional IrDA USB stick is provided with the **clue medical**. The PDF file can then be saved, sent, displayed or printed. Alternatively, the PDF can be transmitted via a Bluetooth capable cell phone directly to the Telovital server for storage.

The device requires that a user is mentally and physically capable of reading and understanding the Patient Operating Instructions. The patient must also be physically capable of pressing the record button and holding the device to his/her chest for an adequate reading.

The **clue medical BASIC** is identical to the **clue medical** in design. The only difference is that the **clue medical BASIC** does not provide the added capability of sending the ECG data via cell

phone directly to the Telovital server, it is only capable of transmission to a local PC or printer. The purpose of this Special 510(k) is to modify the method of wireless data transmission for both the **clue medical** and **clue medical BASIC** to include Bluetooth technology.

Performance Testing

The **clue medical** and **clue medical BASIC** were tested to meet the following standards for its previous clearance in K082013:

- IEC 60601-1, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-1, "Safety Requirements for Medical Electrical Systems"
- IEC 60601-1-2, " Part 1-2: General requirements for safety –Collateral standard: Electromagnetic compatibility –Requirements and tests "
- IEC 60601-2-25, "Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Electrocardiographs"
- IEC 60601-2-47, "Medical Electrical Equipment, Particular requirements for safety, including performance, for ambulatory electrocardiographic systems"

Electrode leadwires were found to be compliant to IEC 60601-1, subclause 56.3(c).

For the purpose of this device modification the device was again tested to meet:

- IEC 60601-1, "Medical Electrical Equipment, General Requirements for Safety
- IEC 60601-1-2, " Part 1-2: General requirements for safety –Collateral standard: Electromagnetic compatibility –Requirements and tests "
- IEC 60601-2-25, "Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Electrocardiographs"
- IEC 60601-2-47, "Medical Electrical Equipment, Particular requirements for safety, including performance, for ambulatory electrocardiographic systems"

Summary of Technological Characteristics:

The only modification to the **clue medical** and **clue medical BASIC** since its previous clearance in K082013 is to enhance the method of wireless data transmission.

Substantial Equivalence Discussion:

The change to the method of wireless data transfer to include Bluetooth does not change the intended use or performance characteristics of the **clue medical** and **clue medical BASIC** as

previously cleared in K082013.

Conclusion:

The modified **clue medical** and **clue medical BASIC** have the following similarities to the devices previously cleared in K082013:

- has the exact same indication for use,
- uses the same operating principle,
- incorporates the same basic device design,
- incorporates the same materials.

Therefore the modification to the **clue medical** and **clue medical BASIC** can be found substantially equivalent to the same devices as cleared in K082013.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2009

Telovital GmbH Telemedizin
c/o Ms. Cherita James
M Squared Associates
901 King St., Suite 200
Alexandria, VA 22314

Re: K083630
Trade/Device Name: clue medical and clue medical BASIC
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (Two)
Product Code: DXH and DPS
Dated: March 26, 2009
Received: March 27, 2009

Dear Ms. James:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

Section 5: Indications for Use Statement

Indications for Use

510(k) Number: K083630

Device Name: **clue medical** and **clue medical BASIC**

Indications for Use:

The **clue medical** and **clue medical BASIC** are handheld, battery operated single channel electrocardiographs intended for recording and transmitting ECG data by patients who are concerned about their heart rhythm. The **clue medical** and **clue medical BASIC** allow the patient to record their ECG data into the device memory and transmit it for display by healthcare professionals.

Specifically, the **clue medical** and **clue medical BASIC** are intended for patients that are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:
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Pounding heart (palpitations)
History of arrhythmia

The **clue medical** and **clue medical BASIC** ECG data is intended to be used by a licensed health care practitioner. These measurements are not intended for any specific clinical diagnosis. The clinical significance must be determined by the physician.

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)

for B Zuckerman

(Division Sign-Off) 4/23/09

Division of Cardiovascular Devices

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