K052343

DEC 7 2005

510(k) Summary

e-San Bluetooth Cradle

Common/Classification Name:

Accessory to Blood Glucose Test System
21 CFR 862.1345

Sponsor:

e-San Ltd.
Attn: Neil Townsend, D.Phil.
Magdalen Centre
Oxford Science Park
Oxford OX4 4GA
United Kingdom

Contact:

Becker & Associates Consulting, Inc.
Attn: Kristin M. Zielinski
2001 Pennsylvania Avenue NW, Suite 575
Washington, DC 20006

A. Legally Marketed Predicate Device

The e-San Bluetooth Cradle is substantially equivalent to the RTX Healthcare® Model RTX3320 Wireless Telehealth Gateway (K041816). The RTX3320 is a telemedicine device that uses Bluetooth technology to transmit data from several types of compatible patient monitors to a hub/gateway for transmission to a compatible data server.

B. Device Description

The device is the e-San Bluetooth Cradle and it is connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and uses short-range low power wireless transmission (Bluetooth V1.2) to send the data to a Bluetooth compatible cellular telephone such as the Nokia Model 6230.

The Cradle is battery powered and fits over and plugs into a 3.5 mm 3-wire stereo socket that is in the end of the OneTouch® Ultra® device.

The Cradle is to be sold over-the-counter (OTC), as it plugs onto OneTouch® Ultra® glucose meter which is also an OTC device.

C. Intended Use

The e-San Bluetooth Cradle is intended to be used by patients at home. It is physically connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and wirelessly sends the signals (via Bluetooth V1.2) to a Bluetooth enabled cellular phone such as the Nokia 6230.

D. Substantial Equivalence Summary

The e-San Bluetooth Cradle has indications for use that are very similar to those of the named predicate device, the RTX Healthcare® Model RTX3320 Wireless Telehealth Gateway. The RTX device is intended to be used with a number of different types of wireless patient monitors that measure parameters such as, but not limited to, weight, blood pressure and blood glucose. The e-San Bluetooth Cradle is currently intended to be used with only one type and model of hard-wired device, the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System.

This premarket notification has described the characteristics of the e-San Bluetooth Cradle in sufficient detail to assure a substantial equivalence determination.

E. Technological Characteristics

The e-San Bluetooth Cradle has technological characteristics that are very similar to those of the RTX as both are Bluetooth V1.2 compatible. The e-San Bluetooth Cradle is battery powered while the RTX is DC-powered via an AC-powered remote supply. Each device uses the same frequency band (2.402 to 2.480 GHz).

F. Testing

The testing that was performed consisted of two types: internal testing using e-San or contractor procedures and specifications; and consensus standard testing. The results were acceptable.

G. Conclusions

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 2005

E-San Limited
c/o Ms. Kristin M. Zielinski
Project Manager
Becker & Associates Consulting Inc.
2001 Pennsylvania Ave. NW.
Suite 575
Washington, DC 20006

Re: k052343
Trade/Device Name: e-San Bluetooth Cradle
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: November 3, 2005
Received: November 3, 2005

Dear Ms. Zielinski:

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.

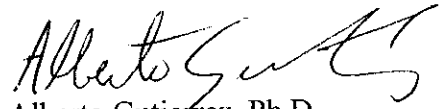
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052343

Device Name: e-San Bluetooth Cradle

Indications For Use:

The e-San Bluetooth Cradle is intended to be used by patients at home. It is physically connected to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and wirelessly sends the signals (via Bluetooth V1.2) to a Bluetooth enabled cellular phone such as the Nokia 6230.

The e-San Bluetooth Cradle serves as the remote communication link between the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and a cellular telephone.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

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