

Special 510(k): Device Modification
Think Positive Diabetes Management System

510(k) SUMMARY

JUN 13 2006

Think Positive (t+) Diabetes Management System

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 modified t+ Diabetes System is substantially equivalent to the previous version of the device (K052343).

B. Device Description

The e-San Bluetooth Cradle 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 t+ Diabetes System allows the blood glucose data to be stored and displayed on a cell phone, and transmitted to a centralized database for storage and display.

C. Intended Use

The intended use of the t+ Diabetes System is for transmission and storage of blood glucose data obtained from a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System.

D. Substantial Equivalence Summary

The t+ Diabetes System has the same fundamental scientific technology and intended use as the predicate device.

E. 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

JUN 13 2006

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

Re: k061328
Trade/Device Name: Think Positive (t+) diabetes Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 12, 2006
Received: May 12, 2006

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.

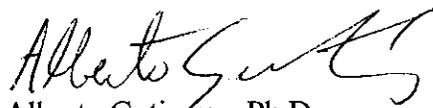
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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): K061328

Device Name: Think Positive (t+) Diabetes Management System

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.

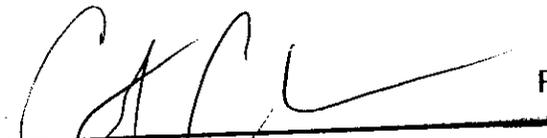
The e-San Bluetooth Cradle serves as the remote communication link between the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and a cellular telephone.

The t+ Diabetes System enables users to store and display data on the cellular phone, and to send data from the cellular telephone to a remote database for storage and display via the internet.

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

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061328