EntraHealth Systems, USA
338 Galloway Valley Ct.
Alpine, CA 91901

K081703

JAN - 8 2009

SUMMARY OF SAFETY AND EFFECTIVENESS
In accordance with 21CFR part 807.92

DEVICE NAME: Myglucohealth Models MGH-1 and MGH-BT1

PREDICATE DEVICE HMD Biomedical "Evolution" blood glucose monitor (reference K072369)

DESCRIPTION: Reference CLASSIFICATION: 862.1345: Blood glucose monitoring systems that include a monitor, control solution and test strips with biosensor.

INTENDED USE:
Systems are intended for the quantitative measurement of the concentration of glucose in whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. Results are plasma calibrated to allow for easy comparison to lab method. The Myglucohealth glucose monitoring systems are not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

SUBSTANTIAL EQUIVALENCE STATEMENT:
The Myglucohealth blood glucose monitoring system is **equivalent in safety and effectiveness** to the HMD Biomedical "Evolution" device by virtue of the following:

1) Similar materials of construction including use of the same PCB, software and strips. Case design is different, however the MGH-BT1 monitor is tested and found to be in compliance to:
   - ISO 15197
   - CB test scheme to IEC/EN 61010-1:2001 and 61010-2-101: 2002

2) Equivalent manufacturing methods as both the MGH and predicate (Evolution) systems (including monitor, control solution and strips) are manufactured by the same entity.

3) Although unlike the predicate, the Myglucohealth MGH-BT1 system provides for the wireless uploading of data from the monitor via Bluetooth transmission to a Bluetooth paired PC or cell phone. However, the wireless transfer of data has been validated and demonstrates a 100% correlation to actual monitor data. A significant number of users of varying demographic ages, gender, education and background were studied.

4) The intended use of the MGH monitors is the same as the predicate device.

Therefore, there are no substantive differences between the products defined in this 510(k) sub-mission and the predicate device.

Signed: _____ Dated: June 4, 2008

Carlos Gonzalez
Regulatory Affairs Consultant to Entra Health Systems, USA
p: (413) 513-6343

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Entra Health Systems, Ltd.
c/o Carlos Gonzalez
7833 Knollbrook Dr.
Pleasanton, CA 94588

JAN - 8 2009

Re: k081703
Trade Name: Myglucohealth Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: December 23, 2008
Received: December 29, 2008

Dear Mr. Gonzalez:

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 (301) 594-3084. 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,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K081703

Device Name: ***Myglucohealth Glucose Monitoring Systems***

Indication For Use:

The Myglucohealth glucose monitoring system provides a quick and easy way for diabetic patients to measure and self-monitor blood glucose levels. The system is comprised of the MGH-BT1 (w/Bluetooth wireless download capability) or the MGH-1 (w/o Bluetooth) blood glucose meter, control solution and test strips that carry a biosensor used for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. The results obtained are plasma calibrated to allow for easy comparison to the laboratory method. Further, results from either meter may be uploaded to a memory device through a standard RS32 connection, or, with the –BT1 model, wirelessly transmitted to a bluetooth capable PC or Cell phone. The Myglucohealth glucose monitoring systems are not to be used for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _x_. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081703