

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION MEMORANDUM  
INSTRUMENT ONLY TEMPLATE**

**A. 510(k) Number:**

K141862

**B. Purpose for Submission:**

New device

**C. Manufacturer and Instrument Name:**

H2 Inc.

Health2Sync Mobile Application

**D. Type of Test or Tests performed:**

Diabetes data management system

**E. System Descriptions:**

1. Device Description:

The Health2Sync Mobile Application and Smart Cable (Mobile Application and adapters) allow the transfer of blood glucose readings (data) from a compatible glucose meter to a smartphone via the Smart Cable. The Application features enable the user to view and analyze blood glucose readings from different meal time periods, other features including lifestyle diary, interpretable graphs option, inviting and sharing data with partners, and emailing reports are available for viewing and analyzing blood glucose readings within the different time slots. The system includes: 1) Health2Sync Mobile Application (through Apple store only), 2) Smart Cable, 3) Smart Cable 3.5mm connector (optional) and 4) Smart Cable and Application Quick Start Guide.

2. Principles of Operation:

The Health2Sync Mobile Applications is a data management tool. The Health2Sync mobile application and smart cable are accessories to compatible blood glucose meters.

The HEALTH2SYNC software application will operate in the following operating environment: (Minimum Requirements)

- iOS Operating System (version 7.0)
- Language: English
- System Device: Apple iPhone 4/4S/5/5S,
- Input – Smart Cable connected to Blood Glucose Meter and the iOS Device audio port.

3. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer webserver, or mobile device? Yes  or No .

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission: Yes  or No .

4. Specimen Identification:

Specimen Identification is based on time and date of testing.

5. Specimen Sampling and Handling:

Not applicable. There is no specimen handling in this device; the device transfers data only.

6. Calibration:

Glucose meter specific. See statement below under section J.

7. Quality Control:

Glucose meter specific. See statement below under section J.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes  or No

**F. Regulatory Information:**

1. Regulation section:

21 CFR §862.2100

21 CFR §862.1345

2. Classification:

Class I \*

Class II

\* A premarket notification (510 (k)) is required for Class I devices meeting the limitations under 21CFR 862.9 (c)(5) For use in diabetes management.

3 Product code:

JQP: Calculator/ Data Processing Module for Clinical Use

NBW: Blood Glucose Test System, Over-the-Counter

4. Panel:

Clinical Chemistry (75)

**G. Intended Use:**

1. Indication(s) for Use:

Health2Sync Mobile Application is data management software that is intended for use in home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. The Health2Sync Smart Cable allows users to upload blood glucose data from compatible FDA cleared meters to the Health2Sync Mobile Application on their iPhone operating system platform.

Health2Sync Mobile Application is not intended to provide treatment decisions nor is it to be used as a substitute for professional healthcare advice.

2. Special conditions for use statement(s):

Over-the-counter use.

**H. Substantial Equivalence Information:**

1. Predicate device name(s) and 510(k) numbers:

Glooko Device System for Glooko Logbook+ Application (K130886)

2. Comparison with Predicate Device:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
	<b>Health2Sync Mobile Application and Smart Cable (K141862)</b>	<b>Glooko Device System for Glooko Logbook+ Application (K130886)</b>
Intended Use	For use by patients with diabetes to sync blood glucose data from compatible meters to mobile Application installed on compatible iOS device(s)	Same
Syncs with Compatible Meters	Yes	Same
Multiple Patients Use	Yes - Multiple patients may use the same device by signing in with unique user ID and password	Same
Data List	List all readings in “Diary”	Same
Daily Activities Records	Yes	Same
Average Data Display	Yes	Same
Change Meter Settings	Does not allow changes to meter settings	Same
Password	Password protection on the Application	Same

<b>Differences</b>		
Item	Device	Predicate
	<b>Health2Sync Mobile Application and Smart Cable (K141862)</b>	<b>Glooko Device System for Glooko Logbook+ Application (K130886)</b>
Operation System (minimum requirement)	iOS 7.0	iOS 5.0
Compatible Blood Glucose Meters	<ul style="list-style-type: none"> <li>• OMNIS Health Embrace BGMS Meter</li> <li>• OMNIS Health Embrace EVO BGMS Meter</li> <li>• Medline EvenCare G2 BGMS meter</li> </ul>	<ul style="list-style-type: none"> <li>• Abbott: FreeStyle Freedom Lite®, FreeStyle Lite®</li> <li>• ARKRAY: GLUCOCARD® 01, GLUCOCARD® VitalTM</li> <li>• Bayer: Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ.</li> <li>• iSens: CareSens N and CareSens N POP</li> <li>• LifeScan: OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini®</li> <li>• ReliOn: ReliOn® Confirm, ReliOn® Prime</li> <li>• Roche: ACCU-CHEK® Aviva, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano</li> </ul>
Connectivity to meter	Audio Port, via Smart Cable	30-pin or lightning 8-pin connector (requires Apple's off-the-shelf Lightning to 30-pin adapter for connection), via MeterSync Cable
Hardware Platform	iPhone 4, 4S, 5 and 5S	<ul style="list-style-type: none"> <li>• iPod touch: 3 and 4G</li> <li>• iPhone: 3GS, 4 and 4S</li> <li>• iPad: iPad 1, 2 and iPad 3G</li> <li>• iPod touch 5G, iPhone 5, iPad mini, and iPad 4G</li> </ul>
Target Levels	High and low blood glucose target levels can be changed: Before Meal, After Meal, Bed Time	High and low blood glucose target levels can be changed: Before Meal, After Meal
Invite Others to View Data through Authorization	Yes (through Partners / Invitations feature)	No

**I. Standard/Guidance Document Referenced (if applicable):**

ISO 14971:2007 – Medical Devices – Application of risk management of medical devices

EN 61000-3-3:2008 – Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current  $\leq 16$  A per phase and not subject to conditional connection

EN 55022:2010 – Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement.

EN 55024:2010 – Information technology equipment. Immunity characteristics. Limits and methods of measurement.

**J. Performance Characteristics:****1. Analytical Performance:**

The performance characteristics listed below as applicable, were established in the specific glucose meter clearance under K113098, K090043, and K113208.

*a) Accuracy:*

See above statement under section J(1).

*b) Precision/Reproducibility:*

See above statement under section J(1).

*c) Linearity:*

See above statement under section J(1).

*d) Carryover:*

See above statement under section J(1).

*e) Interfering Substances:*

See above statement under section J(1).

**2. Other Supportive Instrument Performance Data Not Covered Above:**

1. A usability study was performed with 21 lay users with varying demographic characteristics (age, sex, and education level). The intent of the study was to verify software ease of use and label comprehension. Study participants also completed a questionnaire in response to whether the software, smart cable, and labeling are easy to use. The sponsor concluded that 100% of users were either satisfied or very satisfied with the software, cable, and user manual. The protocol and acceptance criteria of the usability studies were reviewed and found to be acceptable. During this study, data transmission accuracy of the devices was tested, with lay users transmitting data from blood glucose meters to the software. 100% of data was accurately transmitted. Meter memory rollover performance was also verified to be correct on each of the three compatible meters. The results from the usability study demonstrated that the

product performs as intended in the hands of lay users and healthcare professionals. All test results fell within the pre-determined specification parameters.

2. The following documentation related to the software was reviewed and found to be acceptable: level of concern (Moderate), software requirements specifications, architecture design chart, software design specification, traceability analysis, software development environment description, verification and validation testing, device hazard analysis. The sponsor reports that no unresolved anomalies are known to exist in the release version of the software.
3. The results of a Flesch-Kincaid readability assessment were provided, indicating a Grade Level Score of 7.9 for the Health2Sync Application User Manual.
4. The sponsor provided the appropriate documentation certifying that electromagnetic testing had been evaluated and found to be compliant.

**K. Proposed Labeling:**

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.