February 4, 2019

Hygieia, Inc
Robert J Bard
VP Regulatory Affairs
28803 8 Mile Rd, Suite 101
Livonia, Michigan 48152

Re: K181916
Trade/Device Name: d-Nav System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: December 21, 2018
Received: December 26, 2018

Dear Robert J Bard:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

for Tina Kiang Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181916

Device Name
d-Nav® System

Indications for Use *(Describe)*
The d-Nav® System calculates the next dose of insulin to aid in optimizing insulin management.

The d-Nav System contains two user-interactive software elements:
• The patient user interface software is intended for use by adults with Type 2 diabetes as an aid in optimizing insulin management. It resides on a hand-held device, e.g. cellular phone or enabled glucose meter, and is used to enter glucose event data and receive a recommended insulin dose.
• The HCP user interface software tool is intended for use by Health Care Providers (HCPs) to set up the patient software for its intended use. Setup consists of entering the physician-prescribed, patient-specific starting insulin dose instructions (insulin prescription) and sending the information to the patient user software. Insulin instructions include the treatment algorithm (treatment plan), insulin drug, and dose(s).

The d-Nav System also contains the d-Nav Get-Dose Library that provides the next insulin dose.

The System can receive glucose measurement data entered manually into the patient user software or automatically via the cloud from a linked blood glucose meter. The d-Nav Get-Dose Library Recommend Dose function resides locally on the phone while the d-Nav Get-Dose Library Update Insulin Instruction function may reside locally on the phone or be hosted in the cloud. Configurations are as follows:
Model 1: Patient user software resides on a hand-held device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides locally within the device.
Model 2: Patient user software resides on a hand-held device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides in the cloud.
Model 3: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides locally within the device.
Model 4: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides in the cloud.

Use of the d-Nav System is limited to Health Care Providers who have been trained by Hygieia or a Hygieia trained person on the use of the d-Nav System, including setup of the patient's Phone App.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number:	K181916
Date of Summary:	February 4, 2019
Applicant	Hygieia, Inc. 28803 8 Mile Rd, Suite 101 Livonia, MI 48152
Correspondent: Name:	Robert J Bard, JD Hygieia, Inc. 28803 8 Mile Rd, Suite 101 Livonia, MI 48152 248-573-5040 rbard@reglaw.net

Trade Name	d-Nav System K181916	Predicate My Insulin Doser (MID) k082512
Device	Calculator, Drug Dose	Same
Classification Name:	Predictive pulmonary-function value calculator.	Same
Regulation Number	21CFR 868.1890	Same
Product Code	NDC	Same

1.0 DEVICE DESCRIPTION

The d-Nav System is a software-based, prescription-only product designed to provide the next insulin dose recommendation as an aid for personal insulin management. The product integrates the Health Care Provider (HCP) prescribed starting insulin dose instructions with automated dosing guidance to the patient based on comparing regularly measured blood glucose data trends to a device specified target range. The d-Nav System contains two user-interactive software elements; the d-Nav Phone App and the d-Nav Website.

- The Phone App is for use by persons with Type 2 diabetes as an aid in optimizing insulin management. The Phone App resides on a cellular phone and is used by the patient to enter glucose event data and receive a recommended insulin dose. The blood glucose data is obtained from an over-the-counter, cleared Blood Glucose (BG) device and entered into the software system either through manual BG data entry using the Phone App keypad or via a cloud-pushed mechanism from a linked blood glucose meter. The Phone-App allows change in insulin dose recommendations to be sent to the patient without concurrence from the prescriber.

- The d-Nav Website is for use by Health Care Providers that have been trained by Hygieia or a Hygieia trained trainer on the use of Phone App and website to set up the patient's Phone App software for its intended use. Setup consists of entering the physician prescribed, patient-specific starting insulin dose instructions and sending the information to the intended patient's Phone App. Insulin instructions include the treatment algorithm (treatment plan), insulin drug, and dose(s).

The d-Nav System also contains the d-Nav Get-Dose library that provides the next insulin dose.

The System can receive glucose measurement data entered manually into the patient user software or automatically via the cloud from a linked blood glucose meter. The d-Nav Get-Dose Library Recommend Dose function resides locally on the phone while the d-Nav Get-Dose Library Update Insulin Instruction function may reside locally on the phone or be hosted in the cloud.

System Architecture

The following illustrates the architecture of the d-Nav System. Input into the system is glucose data from a glucose meter, either manual or via cloud. The Get-Dose Library is implemented either in the cloud or on the phone.

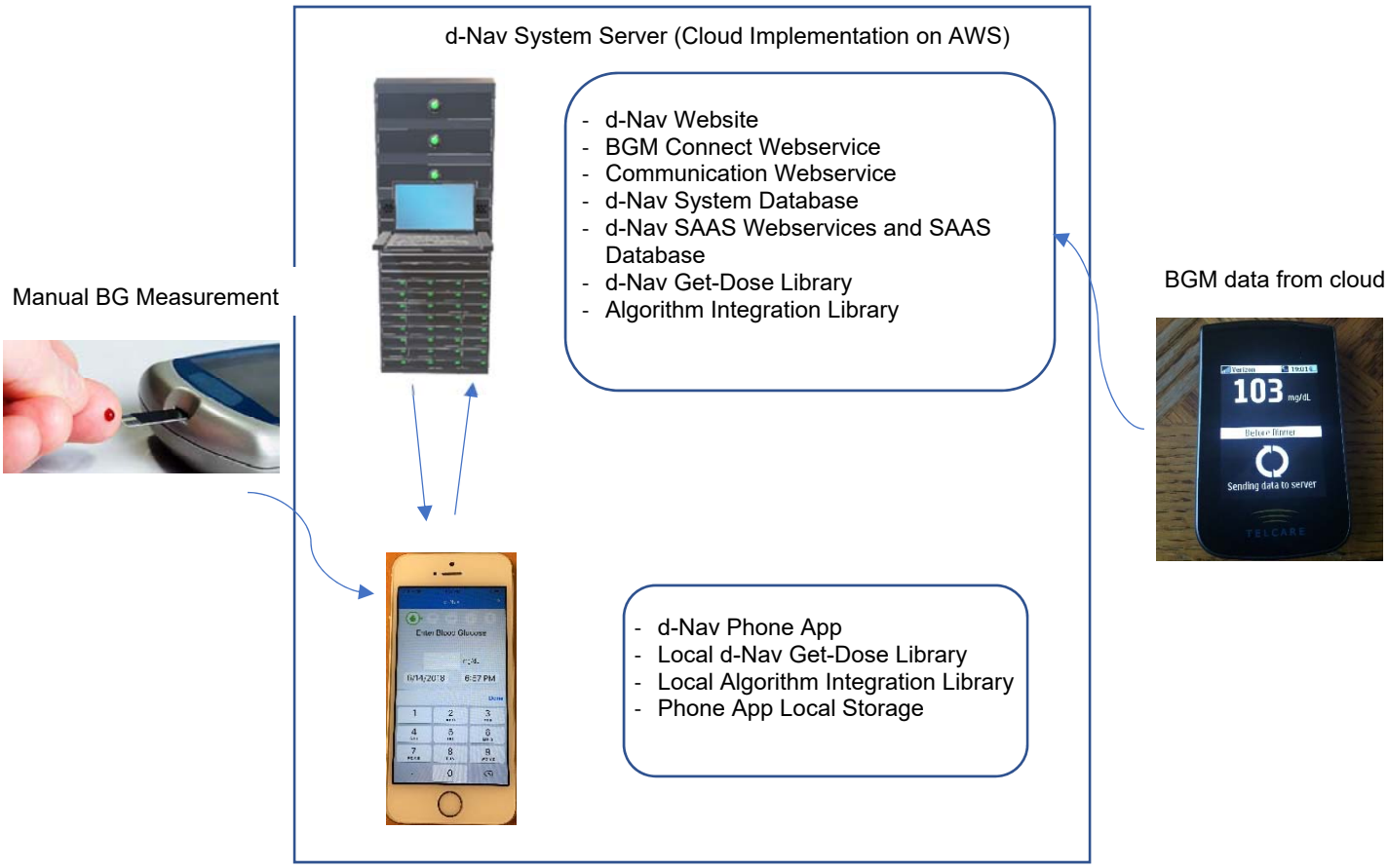

Figure 1. Distribution of Software Components in the d-Nav System

The d-Nav System consists of the following hardware components:

- Mobile Phone: An iOS or Android mobile phone
- d-Nav System Server: Cloud implementation deployed on Amazon Web Services (AWS)

The d-Nav System consists of the following software components:

- d-Nav Website & Webservices: 1) BGM Connect Webservice, 2) Communication Webservice
- d-Nav System Database
- d-Nav SAAS Webservices and SAAS Database
- d-Nav Get-Dose Library
- Algorithm Integration Library
- d-Nav Phone App

Software System Description

The following system context diagram depicts the software components and their interaction within the d-Nav System. This diagram includes illustration of the four (4) d-Nav System Models.

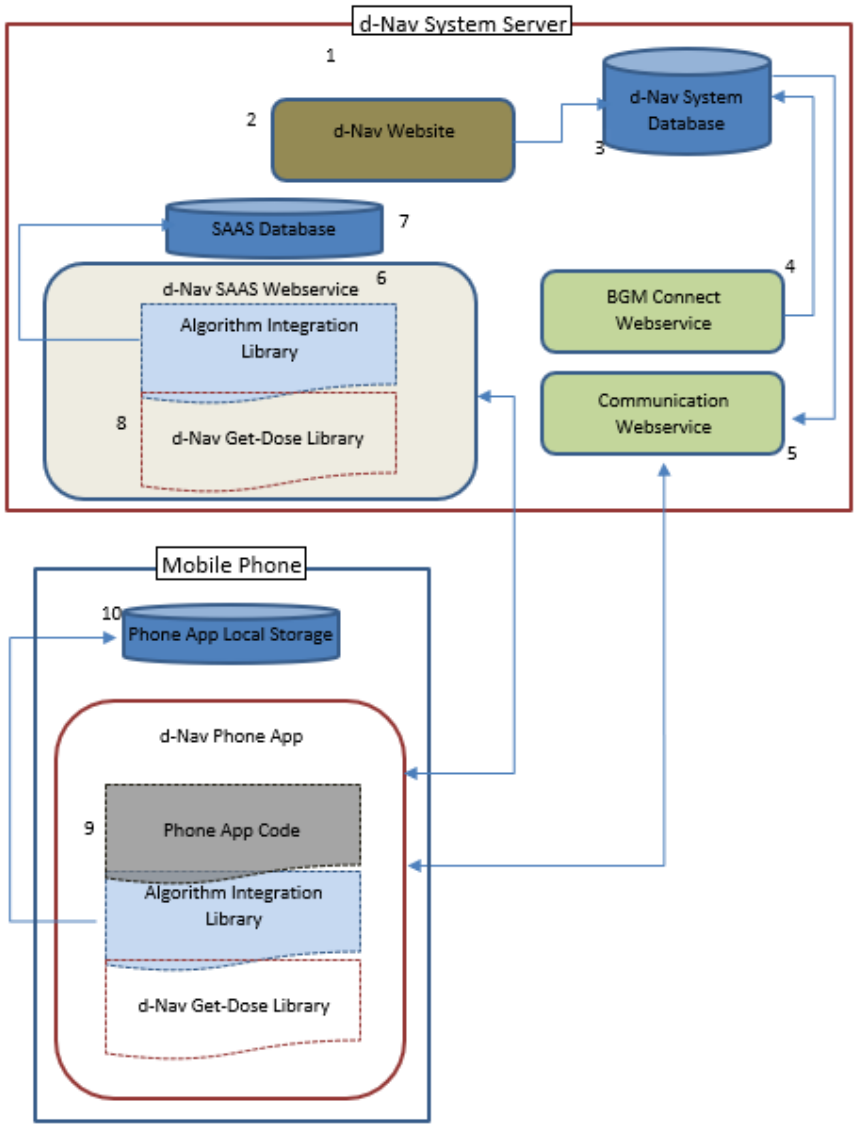

Figure 2. Components in d-Nav System Context

Descriptions for the System Context Diagram Components:

1) **d-Nav System Server:** The d-Nav System Server is a cloud server implemented and deployed on the Amazon AWS S3 server. The Server contains the following software components: 1) d-Nav Website (Microsoft IIS), 2) d-Nav System Database (Microsoft SQL Server), 3) BGM (Blood Glucose Meter) Connect Webservice, 4) Communication

Webservice and 5) d-Nav SAAS Webservice, and 6) SAAS Database (Microsoft SQL Server).

2) **d-Nav Website (Microsoft IIS):** The d-Nav Website is utilized by an authorized Health Care Provider (HCP) to add a new Phone App user to the d-Nav System, set up their physician-prescribed, patient-specific starting insulin dose instructions, and Treatment Plan enable or disable a Phone App, and monitor the Phone App user's insulin and glucose history.

3) **d-Nav System Database:** This SQL database is located on the d-Nav System Server. The d-Nav System Database contains information regarding the system. The database contains 1) website user login information, 2) d-Nav Phone App user information, 3) connected BGM information including the unique relation to users and the records of BG readings sent to the Phone App, 4) records of insulin instructions pushed to the Phone App, 5) records of glucose event data received from the users' Phone App, and 6) insulin instruction updates received from the Phone App (generated by Get-Dose Library).

4) **BGM Connect Webservice:** This webservice is used to send a BG reading to the d-Nav Phone App on the user's phone. The BG reading is received by the webservice either directly from a linked meter or from a BGM manufacturer or other's cloud-based infrastructure.

5) **Communication Webservice:** This webservice provides an endpoint for the d-Nav Phone App to communicate with the d-Nav System Server.

6) **Algorithm Integration Library/d-Nav SAAS Webservice:** In the d-Nav System, there are two instances of the API that enables the d-Nav Get-Dose Library; 1) Algorithm Integration Library in the Phone App and 2) Algorithm Integration Library with the d-Nav SAAS Webservice implementation on the d-Nav System Server. Regardless of the deployment location in the system, the API functions to utilize the otherwise static/stateless d-Nav Get-Dose Library by wrapping it with state and persistence. In the cloud implementation, the d-Nav SAAS Webservice, returns all new data values to the Phone App because the Phone App needs to be in sync with the server.

7) **SAAS Database:** This SQL database is located on the d-Nav System Server. The SAAS Database is utilized solely by the d-Nav SAAS Webservice. The database contains information specific to the user's insulin treatment plan but no user personally identifiable information (PII). The information stored in the database is 1) Phone App instance unique identification values, 2) IDF history including the current insulin instructions and containing the selected treatment plan, insulin drug, and dose(s), and 3) the glucose event records with glucose data, event names, carbs (if applicable), recommended and recorded dose, and timestamp for each record.

8) **d-Nav Get-Dose Library:** Upon receiving a request from the Phone App, the library calculates a new recommended insulin dose or updates current insulin instructions based on

glucose readings, user's current insulin instructions, and history of events and instructions saved in the SAAS Database or Phone App Local Storage (based on system configuration, cloud or local).

9) **d-Nav Phone App:** When the system operation is configured for local usage, the Phone App passes the glucose event data (glucose reading, event type, carb, dose, and timestamp) to the Algorithm Integration Library through a class level function call to request a new recommended dose or update the existing instruction instructions. When the system is configured for cloud server usage, the Phone App call to the d-Nav System Server (to pass a new glucose event data) becomes a REST API[1] request, sent through the internet via a secure SSL connection. This request is received by the d-Nav SAAS Webservice.

10) **Phone App Local Storage:** This SQLite database is located on the mobile phone. The Phone App Local Storage is utilized solely by the Algorithm Integration Library in the Phone App. The database contains information specific to the user's insulin treatment plan but no user PII. The information stored in the database is 1) Phone App instance unique identification values, 2) IDF history including the current insulin instructions and containing the selected treatment plan, insulin drug, and dose(s), and 3) the glucose event records with glucose data, event names, carbs (if applicable), recommended and recorded dose, and timestamp for each record.

2.0 SUBSTANTIALLY EQUIVALENT

The Hygieia d-Nav System is substantially equivalent to the following Dose Calculator device.

Table 1: Predicate Product

Manufacturer and Product	Cleared Predicate Product Regulatory Information
Dimensional Dosing Systems, Inc. My Insulin Doser (MID)/ Intelligent Dosing System (IDS)	K Number: k082512 ProCode: NDC Regulation Number: 21 CFR 868.1890

[1] Representational State Transfer (REST) Application Program Interface (API)

Table 2: Comparison of device under review and its predicates

	ATTRIBUTE	PREDICATE	SUBJECT DEVICE
1	Device name	My Insulin Doser (MID)/ Intelligent Dosing System (IDS)	d-Nav System
2	Device Description	Insulin Dose Calculator	Same
3	Target population	• Health Care Provider (HCP) • Patients with diabetes	Same
4	Where used	• HCP – in professional setting • Patient – at home or mobile	Same
5	Dose calculator algorithm design principle	Response-to-dose single dose	• Single dose for dose decreases • Average response to similarly timed dose over a 1-week period for both increases and decreases
6	UI- containing System components	• HCP SW: IDS • Patient SW: MID	• HCP SW: Website • Patient SW: Phone App
7	Platforms	Web, PC, or Palm Pilot	HCP: Website via PC Patient: iOS, Android Smartphones
8	HCP input process	HCP inputs are entered using the web-based IDS or PC	HCP inputs are entered using the Website through PC
9	HCP inputs	• Single Insulin dose • Desired (Glucose Target) Level determine by prescriber • Current response (e.g. current glucose level) • Insulin drug selection 12 drugs available: o Humalog o Humalog mix 75/25 o Humulin 50/50 o Humulin 70/30 o Insulin o Lantus o Lente o Levemir o Novolin 70/30 o Novolog mix 70/30 o NPH o Regular (R)	• Insulin dose(s) based on Treatment Plan • Basal • Twice daily mixed insulin • Basal-bolus • Basal-bolus with carbohydrate counting • Treatment Plan each with fixed target glucose • Starting insulin sensitivity factor (for basal-bolus plans) • Starting insulin to carbohydrate ratio (for basal-bolus plan with carbohydrate counting) • Insulin drug selection 11 drugs available: o Lantus o Basaglar o Tresiba o Toujeo o Humalog o NovoLog o Apidra o Humalog Mix 75/25 o NovoLog Mix 70/30 o Humulin 70/30 o Novolin 70/30

	ATTRIBUTE	PREDICATE	SUBJECT DEVICE
10	Patient input process	Patient inputs data by mouse and keyboard (or keypad) into software located either on Web, PC, or Palm Pilot Manual inputs	Patient inputs data by keypad into software located on smartphone. Glucose data can be obtained by manual input or transfer from glucose meter via cloud
11	Patient inputs	• Marker: Fasting Glucose, Current (Random) Glucose, HgA1c, or Other Previous dose administered • Insulin drug • Last insulin dose • Desired response (e.g. Fasting Glucose target)	• Glucose: Fasting, Current (e.g. Pre-Meal, Bedtime) • Dose: record insulin dose to reflect actual dose taken • Event Type for current glucose reading (e.g. Breakfast) • Carbs for Basal-bolus with Carb counting
12	Primary outputs	Next insulin dose recommendation	New insulin dose(s) to be used through the next titration period.
13	Secondary outputs for HCP	<u>Patient Dosing Summary</u> Log by date of: • Current Dose • Suggested Dose • Current Marker (e.g. Fasting Glucose reading) • Predicted Marker (predicted / expected response) <u>Patient Dosing with Chart:</u> Log by date/time of: • Unit Dose (current insulin dose) • Current Level (Marker level) • Desired Level (of Marker)	<u>Patient Dosing History</u> Log by date/time of: • Patient Insulin Instruction history • Patient Glucose Event data history Data Export available
14	Primary output for Patient	Next insulin dose recommendation	Same
15	Secondary outputs for Patient (Reports)	<u>Dose Summary Report,</u> a log by date of: • Current Marker (e.g. Fasting Glucose readings) • Current Dose • Suggested Dose • Predicted Marker (predicted / expected response) <u>Patient Dosage with Chart Report</u>: Log by date of: • Unit Dose (current insulin dose) • Current Level (Marker level) • Desired Level (of Marker) Chart plotting by date: various parameters	<u>Patient Dosing History</u> Log by date/time of: • Glucose event data history • Current insulin instructions Each Glucose Event record shows date, time, event type, blood glucose reading, carbs if applicable, and insulin dose, if applicable.
Algorithm			
16	Glucose Target	Adjustable target value	Fixed target range (e.g. glucose 80 – 130 mg/dL) Fixed range based on the Treatment Plan chosen

	ATTRIBUTE	PREDICATE	SUBJECT DEVICE
17	Magnitude of insulin adjustment as a function of target	Proportional to distance from target value	Same
18	Limits on insulin adjustment	≤ ±20%	≤ ±20% but not to exceed pre-determined max. number of units of insulin, except < +30% for increases in Basal-Bolus plans
19	Frequency of insulin adjustment (increase)	Daily increase allowed	Increase occur no greater than weekly
20	Frequency of insulin adjustment (decrease)	Daily decrease allowed	Same

Table 3: Intended/indications for Use Comparison of Subject Device and its Predicates

ATTRIBUTES	PREDICATE	SUBJECT DEVICE
Intended / indications for use	*My Insulin Doser/IDS* calculates the next dose of insulin to optimize a diabetic patient's individual insulin management.	The d-Nav® System calculates the next dose of insulin to aid in optimizing insulin management. The d-Nav System contains two user-interactive software elements: • The patient user interface software is intended for use by adults with Type 2 diabetes as an aid in optimizing insulin management. It resides on a hand-held device, e.g. cellular phone or enabled glucose meter, and is used to enter glucose event data and receive a recommended insulin dose. • The HCP user interface software tool is intended for use by Health Care Providers (HCPs) to set up the patient software for its intended use. Setup consists of entering the physician-prescribed, patient-specific starting insulin dose instructions (insulin prescription) and sending the information to the patient user software. Insulin instructions include the treatment algorithm (treatment plan), insulin drug, and dose(s). The d-Nav System also contains the d-Nav Get-Dose Library that provides the next insulin dose. The System can receive glucose measurement data entered manually into the patient user software or automatically via the cloud from a linked blood glucose meter. The d-Nav Get-Dose Library Recommend Dose function resides locally on the phone while the d-Nav Get-Dose Library Update Insulin Instruction function may reside locally on the phone or be hosted in the cloud. Configurations are as follows: Model 1: Patient user software resides on a hand-held device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides locally within the device. Model 2: Patient user software resides on a hand-held device and uses manual glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides in the cloud. Model 3: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides locally within the device. Model 4: Patient user software resides on a hand-held device and uses automated glucose measurement entry. The Get-Dose Library Update Insulin Instruction function resides in the cloud. Use of the d-Nav System is limited to Health Care Providers who have been trained by Hygieia or a Hygieia trained person on the use of the d-Nav System, including setup of the patient's Phone App.

SE Discussion of Intended Use

Both devices require a prescription from the treating clinician and both are set up by Health Care Providers in a professional setting and used by persons with diabetes in a home setting.

The devices are both intended for use by healthcare professionals and their patients with Type 2 diabetes for calculating insulin dose.

The intended use of the d-Nav System is similar to that of the predicate, as both are software devices that calculate the next dose of insulin to aid in optimizing insulin management.

Both devices calculate the insulin dose based on previous response to aid in optimizing insulin management. The predicate uses a single dose to calculate a dose response. The subject device uses both a single dose to calculate dose reductions and a weekly average based on the relative time point for that insulin dose (i.e. breakfast, or bedtime) to calculate both dose increases and decreases.

Neither device is intended to be a substitute for clinical reasoning.

Substantial Equivalence Discussion of Technological Characteristics

Hygieia has referred to FDA's document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] - Guidance for Industry and Food and Drug Administration Staff (July 28, 2014)" while drafting this evaluation of substantial equivalence with the predicate device.

Technological Characteristics

In terms of technological characteristics, the subject and predicate devices have many similarities. We list the key similarities below. They both:

- Are insulin dose calculator software systems
- Include separate software components for usage by the Health Care Provider (in the professional setting) and for the patient (in the home)
- Use a response-to-dose calculator algorithm that relies on current responses (e.g. blood glucose readings), current insulin instruction dose components, and a target response (e.g. blood glucose level) to calculate the next insulin dose recommendation
- Support usage of a variety of insulin drugs, including basal insulin (e.g. Lantus), premixed insulin (e.g. Humulin 70/30), and bolus insulin drugs (e.g. Humalog, Regular (R))
- Provide a history of responses (e.g. glucose readings) and insulin doses to both Health Care Providers and patients
- Limit the maximum change in the next insulin dose recommendation
- Instruct the patient to alter the next dose recommendation to reflect actual insulin dose taken so that such changes by the patient are recorded in the device memory for review by the Health Care Provider and patient

In terms of technological characteristics, the d-Nav System and predicate devices differ in several details. However, none of these differences rises to the level of being significant as per the previously mentioned FDA Guidance. See Table 2 for Comparison of the two devices.

Discussion of Safety and Efficacy for Certain Differences

The new technology of the d-Nav System does not raise any new issues of safety and/or efficacy when compare to the predicate.

Cloud Feature: The d-Nav Phone App allows for the Get-Dose Library Update Insulin Instruction function to reside in the cloud, which means that, unlike the predicate device, titration may require cloud connectivity. The effect of dose titration is only applicable for the next time a similar dose will be given. For instance, if a breakfast dose resulted in a low glucose reading, then once connected to the cloud, the Get-Dose Library Update Insulin Instruction function will reduce the breakfast dose component. The user will not act upon the new recommendation until the next time they have breakfast which is expected to be in ~24 hours. Hygieia believes that in almost all cases, the user's Phone App will be able to connect to the cloud sometime during that 24 hour period. The labeling advises the prescriber that if the patient is unlikely to have reliable cloud connectivity, the Get-Dose Library should reside on the phone (Model 1 or 3). Conclusion: this new feature of having the titration functionality in the cloud does not raise any new safety or efficacy issues when compared to the predicate device.

Manual vs Connected: The d-Nav Phone App allows the user an option to connect a third-party blood glucose meter via a cloud-to-cloud integration in addition to always allowing the manual entry of glucose if needed. The predicate device does not allow cloud or bluetooth connect and requires manual entry of glucose. Conclusion: the convenience feature in the d-Nav Phone App for blood glucose entry does not raise a new safety concern compared to the predicate device.

Treatments: The d-Nav Phone App and the predicate device support several insulin products (see Table 4 below). Both devices require the prescriber to set the patients' starting insulin dose and have a limit to the next dose titration recommendation. The differences are that the predicate device provides a single titration recommendation at a time and the d-Nav provides four (4) different treatment regimens (basal, twice daily pre-mixed, basal-bolus, and basal-bolus with carbohydrate counting). The d-Nav Phone App includes some safety-check conditions; stops titrations if the patient exceeds an allowable percent deviation from the recommended dose, or if the total daily dose exceeds the prescribers set threshold.

The only other difference is that the d-Nav Phone App supports fast-acting insulin analogs rather than the bolus human insulin Regular (R) for bolus dosing supported by the predicate. Fast-acting insulin analogs have a shorter peak-time and a shorter duration compared to Regular insulin.

Conclusion: the types of regimens and insulins supported by the d-Nav Phone App compared to the predicate device do not raise any new safety or efficacy concerns.

Table 4: Supported Insulin Products

Treatment plan	Predicate device	d-Nav Phone App
Long acting (Basal) insulin	• Lantus • Levemir • Lente • NPH	• Lantus • Tresiba • Basaglar • Toujeo
Pre-mixed insulin	• Humalog mix 75/25 • Humulin 70/30 • Novolog Mix 70/30 • Novolin 70/30	• Humalog mix 75/25 • Humulin 70/30 • Novolog Mix 70/30 • Novolin 70/30
Bolus insulin	• Regular (R)	• Humalog • Novolog • Apidra

3.0 PERFORMANCE DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

Risk Management

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

Cybersecurity Considerations

A cybersecurity evaluation was conducted to ensure the mitigation of cybersecurity risks according to the FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

d-Nav System Verification and Validation

The software Level of Concern for the d-Nav System is Major. Software System, Integration and Unit level verification and validation was performed on the d-Nav System according to FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. (May 11, 2005) for software with a major level of concern.* Test coverage included load testing of the server to ensure acceptable server performance.

Human Factors testing

Human factors testing was performed on the d-Nav System according to FDA Guidance – applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). Testing supported a determination of substantial equivalence.

Comprehensiveness Assessment

The requirements traceability matrix demonstrates that the requirements were fully covered by executing the steps.

4.0 CONCLUSION

The intended use of the d-Nav System is equivalent to that of the predicate, as both are software devices that calculate the next dose of insulin to aid in optimizing insulin management.

Where there are differences between the detailed functionality of the d-Nav System and the predicate, the differences do not raise different questions of safety and effectiveness (see Discussion of Safety and Efficacy for Certain Differences above).

We conclude that the d-Nav System is substantially equivalent to the predicate.