Eli Lilly and Company
Sumitra Ghate
Director, Global Regulatory Affairs - CMC Devices
Lilly Corporate Center
Indianapolis, Indiana 46285

May 17, 2024

Re: K160949
Trade/Device Name: Go Dose System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC

Dear Sumitra Ghate:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 22, 2016. Specifically, FDA is updating this SE letter as an administrative correction. A second product code was inadvertently included.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Juliane Lessard, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6126, Juliane.Lessard@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery,
General Hospital and Human Factors Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 22, 2016

Eli Lilly and Company
Sumitra Ghate
Director-Regulatory CMC Devices
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: K160949
Trade/Device Name: Go Dose System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC, LNX
Dated: November 21, 2016
Received: November 29, 2016

Dear Sumitra Ghate:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160949

Device Name
Go Dose System

Indications for Use *(Describe)*

Go Dose System

The Go Dose System, comprised of the Go Dose and Go Dose Pro applications, is for use in home and clinical settings to aid in the review, analysis, and evaluation of historical blood glucose test values to support type 2 diabetes mellitus management. The Go Dose System is a mobile application for use with iPad or iPhone mobile devices. The Go Dose System provides recommendations for titrating prandial Humalog dosing one meal at a time using blood glucose values entered by the patient. Go Dose and Go Dose Pro applications are not intended to replace the care provided by a licensed health care provider or to provide any diagnosis on patient blood glucose values. Go Dose and Go Dose Pro applications are for prescription use only.

Indications for Use – Go Dose

Go Dose is for prescription use only by persons who are:

- Diagnosed with type 2 diabetes mellitus (DM)
- Aged 18-85 years
- Failing to achieve glycemic targets despite optimization of insulin glargine, with or without metformin
- Requiring treatment intensification with Humalog 100 units per mL (U-100)
- For whom the set blood glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate

Go Dose should be used multiple times per day, as directed by your healthcare provider, for entering blood glucose values and getting Humalog dosing recommendations.

The Go Dose daily adjusted dosing algorithm was tested using Humalog 100 units per mL (U-100) in patients with type 2 diabetes who were also taking insulin glargine, with or without metformin. The algorithm for Go Dose is not designed for the titration of NPH, regular insulin, or basal and analog insulins at concentrations other than 100 unit/mL.

Indications for Use – Go Dose Pro Application

Go Dose Pro is intended for use by health care providers who have experience prescribing mealtime insulin, including providing direction to patients within the scope of a preplanned treatment program for adjustments to prescribed insulin. Health care providers should use the Go Dose Pro to aid in the review, analysis and evaluation of historical blood glucose test values to support diabetes management in patients that meet the following criteria:

- Diagnosed with type 2 diabetes mellitus (DM)
- Aged 18-85 years
- Failing to achieve glycemic targets despite optimization of insulin glargine, with or without metformin
- Requiring treatment intensification with Humalog 100 units per mL (U-100)
- For whom the set blood glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate

The Go Dose design is based on a dosing algorithm that was tested using Humalog 100 units per mL (U-100) in patients with type 2 diabetes who were also taking insulin glargine, with or without metformin. The algorithm for Go Dose is not designed for the titration of NPH, regular insulin, or basal and analog insulins at concentrations other than 100 unit/mL.

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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K160949 510(K) SUMMARY

Manufacturer's Name:	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285
Corresponding Official:	Sumitra M Ghate Director-Regulatory CMC Devices Global Regulatory Affairs CMC
Telephone Number:	317-433-3486
E-mail:	sg@lilly.com

Preparation Date:	December 13, 2016
Trade Name:	Go Dose System
Common or Usual Name:	Dose calculator
Classification Name and Number:	21 CFR 868.1890, Predictive pulmonary-function value calculator Product Code: NDC Additional Product Code: LNX
Primary Predicate Device:	Intelligent Dosing System For Insulin – my Insulin Doser (K082512)
Reference Device:	Accu-chek Advisor Insulin Guidance Software (K043529)

Device Description

The Go Dose System, comprised of Go Dose and Go Dose Pro mobile medical applications (apps), aids patients under the supervision of their health care provider (HCP) in the management of type 2 diabetes mellitus (T2DM).

This medical device system is based on a "paper-based" algorithm approach that was studied for safety and efficacy in 2 multinational, multicenter, randomized, controlled, open-label, parallel-group studies within a single clinical trial, F3Z-MC-IOQC (Trial IOQC) as described in Edelman et al. 2014[1]. This study enrolled adult patients with T2DM who were not under glycemic control after optimizing the dose of insulin glargine for fasting blood glucose, with or without metformin. The medical device provides HCPs and patients with an evidence-based approach to initiate and titrate Humalog® 100 units/mL (insulin lispro) therapy for patients continuing insulin glargine, with or without metformin.

[1] Edelman, S.V. (2014) AUTONOMY: The first randomized trial comparing two patient-driven approaches to initiate and titrate prandial insulin lispro in type 2 diabetes. Diabetes Care 3:2132-2140.

The HCP determines the meal selection for Humalog titration and the starting dose in the Go Dose Pro app, and sends the dose recommendation to the patient's Go Dose app. The patient uses the Go Dose app to view the initial dose recommendation. The Go Dose app uses blood glucose values manually entered by the patient as an input to determine ongoing individualized dose recommendations. This titration process continues until the HCP determines that the dose can be stabilized (i.e., no further titration required) or stopped (i.e., discontinue that dose). At that point, the HCP will determine whether to select a new meal for dose titration, stop any additional use of the Go Dose System, or select additional stable pre-meal dose(s).

Intended Use

Go Dose and Go Dose Pro are for use in home and clinical settings to aid in the review, analysis, and evaluation of historical blood glucose test values to support type 2 diabetes management. Go Dose Pro is intended for use by health care providers who have experience prescribing meal time insulin, including providing direction to patients within the scope of a preplanned treatment program for adjustments to prescribed insulin. Go Dose determines the patients' Humalog doses using blood glucose values entered by the patient. Go Dose and Go Dose Pro are not intended to replace the care provided by a licensed health care provider or to provide any diagnosis on patient blood glucose values.

Indications for Use

Go Dose System

The Go Dose System, comprised of the Go Dose and Go Dose Pro applications, is for use in home and clinical settings to aid in the review, analysis, and evaluation of historical blood glucose test values to support type 2 diabetes mellitus management. The Go Dose System is a mobile application for use with iPad or iPhone mobile devices. The Go Dose System provides recommendations for titrating prandial Humalog dosing one meal at a time using blood glucose values entered by the patient. Go Dose and Go Dose Pro applications are not intended to replace the care provided by a licensed health care provider or to provide any diagnosis on patient blood glucose values. Go Dose and Go Dose Pro applications are for prescription use only.

Indications for Use – Go Dose

Go Dose is for prescription use only by persons who are:

- Diagnosed with type 2 diabetes mellitus (DM)
- Aged 18-85 years
- Failing to achieve glycemic targets despite optimization of insulin glargine, with or without metformin
- Requiring treatment intensification with Humalog 100 units per mL (U-100)
- For whom the set blood glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate

Go Dose should be used multiple times per day, as directed by your healthcare provider, for entering blood glucose values and getting Humalog dosing recommendations.

The Go Dose daily adjusted dosing algorithm was tested using Humalog 100 units per mL (U-100) in patients with type 2 diabetes who were also taking insulin glargine, with or without metformin. The algorithm for Go Dose is not designed for the titration of NPH, regular insulin, or basal and analog insulins at concentrations other than 100 unit/mL.

Indications for Use – Go Dose Pro Application

Go Dose Pro is intended for use by health care providers who have experience prescribing mealtime insulin, including providing direction to patients within the scope of a preplanned treatment program for adjustments to prescribed insulin. Health care providers should use the Go Dose Pro to aid in the review, analysis and evaluation of historical blood glucose test values to support diabetes management in patients that meet the following criteria:

- Diagnosed with type 2 diabetes mellitus (DM)
- Aged 18-85 years
- Failing to achieve glycemic targets despite optimization of insulin glargine, with or without metformin
- Requiring treatment intensification with Humalog 100 units per mL (U-100)
- For whom the set blood glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate

The Go Dose design is based on a dosing algorithm that was tested using Humalog 100 units per mL (U-100) in patients with type 2 diabetes who were also taking insulin glargine, with or without metformin. The algorithm for Go Dose is not designed for the titration of NPH, regular insulin, or basal and analog insulins at concentrations other than 100 unit/mL.

Substantial Equivalence Discussion

Feature	Go Dose System (comprised of Go Dose and Go Dose Pro applications) (K160949)	My Insulin Doser/IDS (K082512)	ACCU-CHEK Advisor Insulin Guidance Software (K043529)
Intended Use	The Go Dose System, comprised of the Go Dose application and Go Dose Pro application, is for use in home and clinical settings to aid in the review, analysis, and evaluation of historical blood glucose test values to support diabetes management. The Go Dose System is a mobile application for use with iPad®, iPhone®, or iPod touch® mobile devices. The Go Dose System provides recommendations for titrating mealtime doses of Humalog, one meal at a time, using blood glucose values entered by the patient. Go Dose and Go Dose Pro are not intended to replace the care provided by a licensed health care provider or to provide any diagnosis on patient blood glucose values. Go Dose and Go Dose Pro are for prescription use only.	My Insulin Doser/IDS allows a person with diabetes to calculate the best next dose of insulin to achieve a personal glucose target.	The software is intended for use in home and clinical settings to aid people with diabetes and their health care providers in review, analysis and evaluation of historical blood glucose test results to support diabetes management, including providing direction within the scope of a preplanned treatment program for adjustments to prescribed insulin, similar to the directions physicians provide to patients as a part of routine clinical practice. The device is not intended to provide any diagnosis on patient results.
Algorithm Feature			
Target Population	Patients aged 18-85 years who have type 2DM, requiring	person with diabetes	patients with diabetes and their health care providers

	treatment intensification with Humalog 100 units per mL (U-100), and for whom the set blood glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate; and their healthcare provider		
Environment of Use	Home under direction of HCP and clinical settings	Home under direction of HCP	Home and clinical settings
Type of Insulin	Prescribed Humalog	Any prescribed insulin	Any prescribed insulin
Software Based	Yes	Yes	Yes
Hardware	Mobile (iPhone, iPad)	Mobile (Palm), desktop PC	Desktop PC
Data Storage	On network computer media	On network computer media	On local computer media
Insulin Dose Calculation	yes	yes	yes
Purpose of Algorithm	To initiate and titrate insulin therapy (to help HCP arrive at stable Humalog dose, titrate additional doses or stop dose) to improve diabetes management	Same	Same
Patient Input variables related to dose calculation	Blood glucose	Blood glucose	• Blood glucose • Carbohydrates • Optional: o Alternate state (allows the user to declare a physiologic condition such as mild stress, mild illness or light exercise) o Entry notes – adds context; can customize
Algorithm Output	Prandial Insulin dosing recommendation	Insulin dosing recommendation	Prandial Insulin dosing recommendation
How is the algorithm employed for a dose recommendation?	The dose recommendation is based on effectiveness of the individual's insulin response, as evident by the post dose blood glucose value. Algorithm is employed by using the current BG to determine that it is safe to dose. Then the last insulin dose, post dose BG, and glucose target range are utilized for the calculation	The dose recommendation is based on the effectiveness of the individual's insulin response, as evident by the BG. The current BG is used to determine if it is safe to dose. Algorithm is employed using the current BG, last dose, current dose, desired glucose target, previous BG and predicted BG for the calculation	The dose recommendation is based on predetermined individualized settings such as glucose target range, insulin to carbohydrate ratio, insulin sensitivity, insulin dosing interval and trends (lifestyle and timing of dosing). The algorithm is employed by using the current BG to see if it is safe to dose and then the settings are used for the calculation
Target blood glucose	HCP determines if glucose target range of 85-114 mg/dL (4.7-6.3 mmol/L) is appropriate for individual	HCP or patient sets expected glucose target.	HCP sets desired glucose target range.

How is starting dose determined?	First dose is calculated based on percentage of total daily long acting insulin; HCP can edit default dose; HCP determines starting dose	HCP determines starting dose	HCP determines starting dose
How is HCP involved in doses/settings?	HCP can adjust doses/settings	Same	Same
How is patient involved with doses/settings?	Patient can edit dose	Same	Same
Information on Diabetes Management	Provides warnings when blood glucose values exceed hypoglycemic or hyperglycemic limits; provides recommended adjustments to the prescribed Humalog dose; tracks blood glucose and insulin data	Provides warnings when blood glucose values and amounts of insulin taken are outside specified range	Provides dose adjustments to prescribed insulin; blood glucose data graphs and reports; tracks non-blood glucose data
Limits for Safety	No dosing recommendation for hypoglycemia; algorithm is constrained to a 1 unit dosage increase per day; maximum Humalog dose is 30 units per dose	No dosing increase for hypoglycemia; percentage constraint based on previous insulin dose	No dosing recommendation for hypoglycemia or if missing manual BG input within a meal time window
Warnings	Hypoglycemia and Hyperglycemia; aberrant dose recommendation; Uses numeric "fixed" targets for corresponding numeric alerts	Hypoglycemia, Hyperglycemia; warnings are presented when values are out of range and/or insulin doses are , or > 20% of the most recent dose	Hypoglycemia, Hyperglycemia; when safety limits for BG and insulin are exceeded

Abbreviations: BG=blood glucose; DM = diabetes mellitus; IDS = Intelligent Dosing System; PC= Personal Computer; HCP= health care provider

Discussion of Differences

There are two key differences between the indications for use of the Go Dose System and the predicate (K082512) and reference (K043529) devices:

- The predicate device and reference device do not have a specific age range for the intended population in the indications for use statement. The restriction of the intended population is a subset that aligns with the clinical testing and prescribing information for Humalog insulin. Therefore, this specification of the intended population is needed to align with the drug for which this device can be used with.
- The predicate and reference devices contains a single version either intended for use by the patient or the health care provider. The Go Dose System contains 2 versions – the Go Dose Pro and Go Dose. One version is for the health care provider and one version is for the patient. Both versions of the device underwent the same performance and software testing to ensure functionality. This does not raise any new questions of safety or effectiveness compared with having different accesses and privileges within the same application.

However, the intended populations and intended use are similar. The differences in the indications for use do not raise any new questions of safety or effectiveness.

An outline of the similarities between Go Dose System and the predicate (K082512) is given below:

- Devices use patient blood glucose value to calculate a recommended insulin dose.
- Devices are used by similar target populations.
- Devices are prescription use and used in home and clinical settings.
- Devices are stand-alone software-based.
- Stored data resides on computer media.
- Information for diabetes management is provided.
- HCP oversight of information is provided to patients.

The following differences are noted but are not considered to raise new questions regarding safety or effectiveness:

- Go Dose System network data is stored on a cloud-based platform.
- Go Dose System is for use on iOS mobile platforms.

The ACCU-CHEK Advisor Insulin Guidance Software (K043529) (reference) utilizes similar scientific technology for the purposes of providing insulin dosing adjustments. The ACCU-CHEK Advisor software is provided as a reference device for insulin dose adjustment algorithms providing dosing recommendations meant to be used by patients over time to determine optimal insulin dosing.

Performance Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This software device was considered as a "major" level of concern.

The Go Dose System submission included a Safety Assurance Case to organize and support a comprehensive evaluation of hazards.

The results of Human Factors testing have demonstrated that the GoDose System is substantially equivalent to the predicate device.

Clinical Tests

There were no clinical performance studies conducted using the Go Dose Mobile Medical Application System. However, the algorithm employed in the Go Dose System was studied using a paper based method in clinical trial IOQC, which consisted of 2 multinational, multicenter, randomized, controlled, open-label, parallel-group studies under one protocol within a single clinical trial, F3Z-MC-IOQC (Trial IOQC) as described in Edelman et al. 2014[2]. This study enrolled adult patients with T2DM who were not under adequate glycemic control with an insulin glargine dose optimized for fasting blood glucose, with or without metformin.

Conclusions

The Go Dose System design was evaluated in comparison to the predicate device relative to the intended use, indications for use, intended users, and intended use environment.

The non-clinical evaluation included review of applicable standards, guidance, and a safety assurance case approach that incorporates clinical risk per ISO 14971 and cybersecurity risks. The results of the software verification indicate the software specifications were correctly implemented. The results of the summative validation study and supplemental

[2] Edelman, S.V. (2014) AUTONOMY: The first randomized trial comparing two patient-driven approaches to initiate and titrate prandial insulin lispro in type 2 diabetes. Diabetes Care 3:2132-2140.

validation study indicate the predetermined acceptance criteria were met. The safety assurance case approach was used to organize and support a comprehensive evaluation of hazards as an aid to the development team, ultimately resulting in the residual risk assessment. The residual risk assessment confirms that the remaining risk is outweighed by the benefit provided by the Go Dose System.

The conclusions drawn from the nonclinical and clinical tests conducted, demonstrate that the device is substantially equivalent to the legally marketed predicate device, My Insulin Doser/IDS (K082512).