DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 7, 2017

Lifescan Europe, A Division Of Cilag Gmbh
% Kirsten Franco
Sr. Regulatory Affairs Program Lead
Lifescan Inc.
965 Chesterbrook Blvd
Wayne, Pennsylvania 19087

Re: K163357
Trade/Device Name: One Touch Via™ On-Demand Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: OPP, LZG
Dated: May 3, 2017
Received: May 5, 2017

Dear Kirsten Franco:

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,

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)*

K163357

Device Name
One Touch Via™ On-Demand Insulin Delivery System

Indications for Use *(Describe)*
The One Touch Via™ On-Demand Insulin Delivery System is intended for subcutaneous, bolus delivery of insulin for the management of diabetes mellitus in adult persons requiring insulin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 - 510(k) Summary

This 510(k) summary is provided as part of this Premarket Notification in compliance with 21 CFR Section 807.92.

510(k) Submitter:	LifeScan Europe, a division of Cilag GmbH Gubelstrasse 34 CH-6300 Zug Switzerland
Contact:	Kirsten Stowell Franco Sr. Regulatory Affairs Program Lead 965 Chesterbrook Blvd Wayne, PA 19087 Phone: 484-328-6043 Fax: 855-261-4885 Email: kfranco5@its.jnj.com
Date Prepared:	May 2, 2017
Device trade name:	OneTouch Via™ On-Demand Insulin Delivery System
Device Common Name:	Disposable Insulin Infusion Pump
Device classification:	Infusion Pump Product Code: OPP (primary); LZG (secondary) 21 CFR 880.5725 Class II 80 - General Hospital
Legally marketed predicate device:	K111924 FINESSE™ Personal Insulin Delivery System
Predicate device classification:	Infusion Pump Product Code: OPP (primary); LZG (secondary) 21 CFR 880.5725 Class II

Device Description

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The OneTouch Via™ On-Demand Insulin Delivery System (IDS) consists of a sterile, non-pyrogenic, single-use, external, disposable, ambulatory, Insulin Delivery Device (IDD, "Patch," "the Patch"), reusable Inserter, a single use, non-pyrogenic, sterile, syringe and needle ("Fill Syringe"), a Dose Count Reminder Card, and a sheet of Change by Stickers. The device is intended for subcutaneous delivery of insulin and is adhered to the skin for up to 72 hours using a biocompatible adhesive.

The IDD is a manual, user filled, positive volume displacement, bolus dosing pump. The Inserter is used to place the IDD on the skin and simultaneously implant the cannula into the subcutaneous tissue. The Fill Syringe is used by the patient to fill the IDD with insulin prior to deployment on the body. The Fill Syringe and IDD have a maximum capacity of 2ml. The Dose Count Card is utilized as a reminder by the patient during the dosing session. The Change by Sticker indicates to the user the day and time (AM or PM) to remove and replace the patch.
The OneTouch Via™ IDS is constructed from biocompatible plastics, elastomers, and stainless steel.

Indications for Use

The OneTouch Via™ On-Demand Insulin Delivery System is indicated for the subcutaneous bolus delivery of insulin for the management of diabetes mellitus in adult persons requiring insulin.

Comparison to the Predicate Device

The purpose of this submission is to describe minor modifications in component design for improved manufacturability associated with the relocation and increased automation of the manufacturing of the OneTouch Via™ On-Demand Insulin Delivery System. This manufacturing relocation required no major changes in manufacturing process technologies. Additional minor changes from the predicate device include minor changes to labeling content and format, including product trade name and branding changes. The changes from K111924 include:

Design Changes:

- Fill Syringe & Needle material and design changes;
- Packaging design and material change
- Internal component dimensional changes
- Needle Handle/Clip Design Change;
- Minor material grade changes and/or supplier change;

- Minor changes to labeling content and format, including product trade name and branding changes.

Process / Tooling / Supplier Changes:

- Component mold tool changes;
- Contract sterilization supplier change

The intended use and Indications for Use of the subject device, as described in the labeling, are **identical** to the predicate device; there is no change since clearance under K111924. The System technological characteristics, performance characteristics, and the user interface remain unchanged.

Technological Characteristics

The OneTouch Via™ IDS meets the FDA description of a pump, infusion, insulin bolus as established in product codes 80-OPP, and pump, infusion, insulin as established in product code 80-LZG. The IDD is identical to other insulin delivery devices in that it uses a positive volume displacement type of manual piston to precisely deliver discrete doses of insulin from the internal reservoir. The IDD does not contain any power sources; it is non-electrically powered. The IDD piston is actuated by the mechanical action of the user's fingers pressing on the buttons. It contains a reservoir to hold insulin. The IDD has a single lumen flexible catheter/cannula that delivers the insulin to the subcutaneous tissues. The IDD may be worn for up to 72 hours. The IDD is used by a patient to deliver rapid acting insulin, i.e., insulin delivery requires competent human interaction to actuate the buttons to deliver insulin.

The proposed OneTouch Via™ IDS is substantially equivalent to the Calibra Medical FINESSE™ Personal Insulin Delivery System cleared under 510(k) K111924, as both devices share the following:

- Intended Use / Indications for use
- Fundamental Scientific Technology
- Principles of Operation
- Conditions of Use

Additionally, the labeling and device materials are similar between the proposed and marketed devices.

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Non-Clinical Performance Data

Appropriate verification activities were completed as recommended by the *FDA Guidance for Industry and FDA Staff: Total Product Life Cycle: Infusion Pump (Issued December 2, 2014)* and other applicable guidance. The following performance testing was identified by appropriate risk management activities conducted in accordance with *ISO 14971:2007: Medical devices – Application of risk management to medical devices*.

Insulin compatibility and stability studies have demonstrated the chemical, physical, and microbiological stability of insulin in the IDD for the period of time specified in the labeling.

The biocompatibility evaluation for the OneTouch Via™ IDS was conducted per *FDA Guidance for Industry and FDA Staff: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Issued June 16, 2016).* The following Biocompatibility Testing was completed as part of this evaluation:

- *Cytotoxicity testing*
- *Sensitization testing*
- *Intracutaneous reactivity testing*
- *Acute systemic toxicity testing*
- *Subacute/Subchronic Toxicity*
- *Genotoxicity*
- *Implantation*
- *Material Mediated Pyrogen*
- *Hemolysis*

Design verification studies per test methods and acceptance criteria previously established for the predicate device were conducted on finished devices which were representative of commercial device have demonstrated the function, wear and mechanical reliability of the device for the intended period of time. Testing included dimensional inspection, IDD performance testing (at nominal and extreme environmental conditions), alarm function, leak testing, cannula function, needle function, chemical compatibility, packaging testing, fluid ingress, and adhesive performance. Design verification studies including chemical exposure, cleanability and functional testing have also demonstrated the function and reliability of the Inserter accessory. Design verification testing has also been conducted demonstrating the

function and reliability of the Fill Syringe accessory. Human factors studies have been completed that demonstrate labeling comprehension and usability.

The results from this non-clinical performance testing demonstrate that the technological characteristics and performance criteria of the proposed device are comparable to the predicate device and that the proposed device performs in a manner equivalent to the predicate device (K111924).
No clinical performance data is required to validate the intended uses and user needs of the system.

In accordance with the *FDA guidance for Industry and FDA Staff: Infusion Pumps Total Product Life Cycle (Issued December 2, 2014),* a Safety Assurance Case has been developed for the IDS. The Safety Assurance Case (SAC) provides a structured argument in Goal Structuring Notation (GSN) format, which presents a top level claim, supported by a body of valid scientific evidence, and context that provides an organized case that the IDS adequately addresses hazards associated with its intended use within its environment of use. The scope of the Safety Assurance Case is to demonstrate that the IDS is acceptably safe for the intended use.

The following three top level argument structures were used to support the top level claim:

1. Argue through the claim and evidence process that risks to health associated with the use of the IDS have been adequately mitigated.

2. Argue through the claim and evidence process that design requirements and specifications are adequate for the IDS.

3. Argue through the claim and evidence process that IDS is reliable throughout the normal life of the product.

No additional hazards or harms were identified during the construction and review of the Safety Assurance Case. This process did, however, provide clarity between the linkages and safety aspects of the Design History File. In conclusion, the Safety Assurance Case presents claims, arguments and evidence to collectively substantiate the top-level argument that the system is acceptably safe for its intended use.

Substantial Equivalence Conclusion

The proposed OneTouch Via™ On-Demand Insulin Delivery System uses the same technology, indications for use, and modes of operation as the predicate FINESSE™

Section 5 - 510(k) Summary

Personal Insulin Delivery System (K111924). The proposed modifications do not affect the intended use or technological characteristics of the predicate device. Performance bench testing demonstrated that the subject device met all the existing device specifications, thereby demonstrating that the device is as safe, as effective, and performs as well as the predicate device (K111924).