November 13, 2024

CeQur SA
Michael Simpson
Vice President, RA/QA/Engineering
Ebenaustrasse 10
Horw Luzern, 6048
Switzerland

Re: K243273
Trade/Device Name: CeQur Simplicity™ On-Demand Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: OPP
Dated: October 14, 2024
Received: October 16, 2024

Dear Michael Simpson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

k243273

Device Name

CeQur Simplicity™ On-Demand Insulin Delivery System

Indications for Use *(Describe)*

The CeQur Simplicity™ 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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510(k) #:

510(k) Summary

Prepared on: 2024-10-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	CeQur SA
Applicant Address	Ebenaustrasse 10 Horw Luzern 6048 Switzerland
Applicant Contact Telephone	404-276-5449
Applicant Contact	Mr. Michael Simpson
Applicant Contact Email	mike.simpson@cequr.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CeQur Simplicity™ On-Demand Insulin Delivery System
Common Name	Infusion pump
Classification Name	Pump, Infusion, Insulin Bolus
Regulation Number	880.5725
Product Code(s)	OPP, LZG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233447	CeQur Simplicity™ On-Demand Insulin Delivery System	OPP
K093065	Finesse Personal Insulin Delivery Patch, Model FG-2000	OPP
K163357	OneTouch Via™ On-Demand Insulin Delivery System	OPP

Device Description Summary

21 CFR 807.92(a)(4)

The CeQur Simplicity™ 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"), 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 4 days (96 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 Change by Sticker indicates to the user the day and time (AM or PM) to remove and replace the patch. The CeQur Simplicity™ IDS is constructed from biocompatible plastics, elastomers, and stainless steel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CeQur Simplicity™ On-Demand Insulin Delivery System is intended for subcutaneous, bolus delivery of insulin for the management of diabetes mellitus in adult persons requiring insulin.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same as for the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics of the subject device are identical to the predicate device with the exception of dimensional changes to the predicate device pump mechanism, which enable the subject device to deliver a 1U bolus of insulin per pump button depression.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The performance data reported in this 510(k) demonstrate that the proposed device modifications do not raise different questions of safety and effectiveness than those for the predicate device, and that the subject device is as safe and effective as the predicate device.

The subject device is therefore deemed to be substantially equivalent to the predicate device.