December 19, 2025

Diabeloop
Erik Huneker
Director QA, RA & CA and co-founder
17 rue Felix Esclangon
Grenoble, 38000
France

Re: K251152
Trade/Device Name: DBLG2
Regulation Number: 21 CFR 862.1356
Regulation Name: Interoperable Automated Glycemic Controller
Regulatory Class: Class II
Product Code: QJI
Dated: April 3, 2025
Received: April 14, 2025

Dear Erik Huneker:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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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)*
K251152

Device Name
DBLG2

Indications for Use *(Describe)*
DBLG2, a mobile application with algorithm technology, is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) insulin infusion pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when glucose values are predicted to exceed a predefined threshold. To do this, the DBLG2 software takes into account the patient's profile, glycemia (current and predicted), announced meals and physical activities.

DBLG2 is intended for the management of type 1 diabetes mellitus in persons 12 years of age and greater.

DBLG2 is intended for single patient use.

DBLG2 is Rx - For Prescription Use Only.

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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# UD-FDA-3881_12-25-13 release 1

UD-FDA-3881_12-25-13

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**Signatory :**
1. Author - VICENTE Alexandre - R&D Project Coordinator digitally signed on 14/12/2025 10:30
2. Reviewer - HUNEKER Erik - Director QA, RA & CA digitally signed on 14/12/2025 12:37
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**Record name:** DBLG2US-RA-SUM-001-Rev5

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

## 1. Submitter information

| | |
|---|---|
| Sponsor: | Diabeloop SA<br>17 Rue Félix Esclangon<br>38000 Grenoble<br>France |
| Contact Person: | Erik Huneker, Director QA, RA & CA and co-founder |
| Email: | fda@diabeloop.fr |
| Phone: | +33 (0)4 76 09 54 18 |

## 2. Proposed device

| | |
|---|---|
| Device Classification Name: | Interoperable Automated Glycemic Controller (iAGC) |
| Device Classification: | Class II, 21 CFR 862.1356 |
| Product Code: | QJI |
| Device Proprietary Name: | Diabeloop DBLG2 |

## 3. Predicate Device

| | |
|---|---|
| Device Name: | Tidepool Loop |
| Manufacturer: | Tidepool |
| Premarket Notification #: | K203689 |
| Device Classification Name: | Interoperable Automated Glycemic Controller (iAGC) |
| Device Classification: | Class II, 21 CFR 862.1356 |
| Product Code: | QJI |

## 4. Date Prepared: 12/19/2025

# 5. Device description

Diabeloop DBLG2 is an Android application installed on patient personal mobile phone, intended for managing glucose levels in people with type 1 diabetes, using a hybrid closed loop approach (automated insulin delivery). It is designed to be connected with a compatible Automated Controller Enabled (ACE) insulin pump and integrated Continuous Glucose Monitors (iCGM).

DBLG2 has a regulation algorithm to automatically manage the patient's blood glucose level. It takes as input glycemia value received from the CGM, personal patient medical parameters and patient input related to meals and physical activities, and it calculates every 5 minutes the amount of insulin to deliver in order to keep the patient in the normoglycemia bounds. It sends this information to the pump that automatically delivers this quantity of insulin.

The software can ask the pump to deliver:

- A meal bolus
- A correction bolus (small amount of insulin)
- A basal rate over a given period of time.

The software can also ask the patient to take a calculated amount of carbohydrates if the system determines that the patient would go into hypoglycemia even if the insulin basal rate is brought down to zero.

DBLG2 acts mostly by modulating the basal rate of insulin delivery, but in some cases can deliver, automatically, correction boluses. It includes a patient-confirmed meal bolus calculator that simplifies meal dosing by allowing the patient to enter their meal carbohydrate amount while the system retrieves the patient's personalized insulin dosing parameters from their profile. The system calculates and displays a recommended meal bolus dose, which the patient must review and confirm before delivery is initiated.

In addition, DBLG2 has a self-learning module that applies improvements to the patient's algorithm parameters, based on estimated glycemia history and insulin delivery quantities, from the patient's history.

DBLG2 is designed to be secure, with by-design and structural security mechanisms that prevent from both hypoglycemia and hyperglycemia

- Hypoglycemia: by detecting an existing or upcoming hypoglycemia:
  - The algorithm cuts down insulin delivery if a risk of hypoglycemia exists within the next fifteen minutes, the system will ask the user to take carbohydrates (by an alert).
  - If the patient is in hypoglycemia below 55mg/dL (= 3.1mmol/L), an alarm is triggered.
- Hyperglycemia: the algorithm orders the delivery of insulin correction bolus to reduce the glycemia.

The software also guarantees patient's safety by returning to the pre-programmed basal pattern if the automatic regulation cannot be done for any reason (including loss of communication with the CGM or pump) or if the patient wishes to return to manual control by stopping the automatic regulation.

The algorithm includes appropriate alerts/alarms in case of any malfunction of one of the components.

# 6. Indication for Use

DBLG2, a mobile application with algorithm technology, is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) insulin infusion pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when glucose values are predicted to exceed a predefined threshold. To do this, the DBLG2 software takes into account the patient's profile, glycemia (current and predicted), announced meals and physical activities.

- DBLG2 is intended for the management of type 1 diabetes mellitus in persons 12 years of age and greater.
- DBLG2 is intended for single patient use.
- DBLG2 is Rx - For Prescription Use Only.

**Contraindications**

- DBLG2 should not be used by anyone who is unable to notice alerts, alarms, and reminders because of physical limitations, such as severe uncorrected hearing impairment or severe uncorrected problems of visual acuity.
- DBLG2 should not be used by anyone who is unwilling or unable to follow the instructions for use.
- DBLG2 should not be used by anyone that is unable to maintain contact with their healthcare provider.
- DBLG2 should not be used by patients suffering from a serious illness or undergoing treatment that might significantly impair diabetes physiology (e.g. irregular treatment by steroids) and which might interfere with the medical device
- DBLG2 should not be used by patients receiving a total daily dose of insulin lower than 8 units.
- DBLG2 should not be used by patients using any insulin that is not 100U/mL rapid-acting insulin analog.

**MR Unsafe:** DBLG2 should not be used during Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. Components of the DBLG2 system may not have been tested in magnetic fields and heat could damage the compatible iCGM or ACE pump being used with DBLG2 and prevent accurate sensor glucose readings or accurate insulin delivery. This could result in overdelivery or under-delivery of insulin, which can lead to low or high blood glucose. Please follow Healthcare Provider instructions and refer to the individual component manuals for more information.

**Clinical Warnings:**

The safety and effectiveness of the DBLG2 System have not been tested or approved for the following categories of people:

- Patients with type 2 diabetes
- Patients with highly unstable diabetes
- Patients with gestational diabetes
- Pregnant women with type 1 diabetes
- Patients whose pancreas has been removed or is not functioning altogether
- Patients with severely altered renal function (creatinine clearance < 30 mL/min)
- Patients with a decreased feeling of hypoglycemia symptoms
- Patients with islet/pancreas transplants
- Patients on dialysis
- Critically ill patients

# 7. Comparison to Predicate Device

DBLG2 software is substantially equivalent to the predicate device, Tidepool Loop, as cleared in K203689. The table below shows a comparison of the technological, functional, and performance characteristics between the subject and predicate devices.

**Comparison Table, Diabeloop DBLG2 vs. Tidepool Loop**

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| Regulatory Information | | | |
| Product Code | QJI | QJI | Same |
| Regulation Name | 21 CFR 862.1356, Interoperable Automated Glycemic Controller | 21 CFR 862.1356, Interoperable Automated Glycemic Controller | Same |
| Indications for Use, User population | | | |
| Indication for use | Tidepool Loop is a mobile application and algorithm technology that is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend and deliver correction boluses when glucose values are predicted to exceed user configurable thresholds.<br><br>Tidepool Loop is intended for the management of Type 1 diabetes mellitus in persons six years of age and greater.<br><br>Tidepool Loop is intended for single | DBLG2, a mobile application with algorithm technology, is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) insulin infusion pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when glucose values are predicted to exceed a predefined threshold. To do this, the DBLG2 software takes into account the patient's profile, glycemia (current and predicted), announced meals and physical activities. | Equivalent.<br><br>Target population age is more restrictive for DBLG2 than for Tidepool Loop which is more generic. |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | patient use.<br><br>Tidepool Loop is Rx - For Prescription Use Only. | DBLG2 is intended for the management of type 1 diabetes mellitus in persons 12 years of age and greater.<br><br>DBLG2 is intended for single patient use.<br><br>DBLG2 is Rx - For Prescription Use Only. | |
| Prescription Use | Yes | Yes | Same |
| Intended population | Type 1 diabetes mellitus in persons six years of age and greater. | Patients with type 1 diabetes who are more than 12 years of age. | Same |
| Environment of use | Home environments | Home environments | Same |
| Number of Users | Single user only | Single user only | Same |
| Technological characteristics | | | |
| Principle of operation | Tidepool Loop predicts glucose levels up to 6 hours in the future (the approximate duration of insulin action for U-100 rapid-acting insulin) based on prior iCGM readings, insulin delivery history, and user input (e.g., carbohydrate intake and | DBLG2 software has a regulation algorithm to automatically manage the patient's blood glucose level, making glucose level prediction up to 5 hours in the future and insulin delivery prediction up to 2 hours. It takes as input glycemia value received from | Equivalent.<br><br>The time associated with glucose level prediction on DBLG2 software is more conservative than Tidepool Loop. |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | exercise) and uses that prediction to adjust insulin delivery.<br><br>Tidepool Loop can be used to adjust or suspend basal insulin delivery every 5 minutes and deliver correction boluses of insulin based on actual and predicted CGM sensor readings.<br><br>Users must manually deliver meal boluses they can calculate using the Tidepool Loop Bolus Recommendation Tool (TLBRT) and can manually adjust insulin delivery (change basal rates and deliver insulin boluses) when Tidepool Loop is active. | the CGM and patient input related to meals and physical activities and it calculates the amount of insulin to deliver. It sends this information to the pump that automatically delivers this quantity.<br><br>DBLG2 can be used to adjust or suspend basal insulin delivery every 5 minutes and automatically deliver correction boluses of insulin based on actual and predicted CGM sensor readings.<br><br>Users must manually confirm meal boluses, when calculated by the DBLG2 recommendation or determine and enter the boluses manually, and can also adjust insulin delivery themselves by modifying basal rates and administering additional insulin boluses as needed. | |
| Type of Algorithm | Hybrid Closed Loop - predictive control | Hybrid Closed Loop - predictive control | Same |
| Compatible iCGM | Dexcom G6 | Dexcom G6 | Same |
| Compatible ACE Pump | An ACE pump that has the specifications and meets the pre-specified acceptance criteria for software, cybersecurity, device interoperability, human factors, labeling, and training materials as described in | An ACE pump that has the specifications and meets the pre-specified acceptance criteria for software, cybersecurity, device interoperability, human factors, labeling, and training materials as described in | Equivalent.<br><br>Both require cleared ACE Pumps. |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | SOP-0016, "Tidepool Loop Connected Device Integration and Validation Process and Plan," and SOP-0018, "Tidepool Loop Regulatory Determination Process." Tidepool Loop must not be distributed until the pre-specified acceptance criteria in the SOPs are met. | DBL-RD-SPECSUP-007 ACE pump specifications.<br><br>Diabeloop DBLG2 must not be distributed until the pre-specified acceptance criteria in the DBL-RD-SPECSUP-007 are met. | |
| Device Design or Material | Tidepool Loop is a mobile application and a Software as Medical Device (SaMD) installed on a host mobile device | Diabeloop DBLG2 is a mobile application and a Software as Medical Device (SaMD) installed on a host mobile device | Same |
| Algorithm Platform | iPhone | Android | Equivalent.<br><br>Both the subject and predicate devices have equivalent risks and mitigations for each use profile. No new or modified risks. |
| Functional characteristics | | | |
| User-controlled Target Range Settings | Customizable settings<br><br>Correction Range: 87 - 180 mg/dL | Customizable settings<br><br>Target glucose level and thresholds :<br>• Target glucose level: 100 - 130 mg/dL (default value 110 mg/dL)<br>• Hyperglycemia threshold: 170 - 220 mg/dL (default value 180 mg/dL) | Equivalent.<br><br>The DBLG2 software uses a glucose target set point (110 mg/dL by default) with customizable hypoglycemia and hyperglycemia thresholds, rather than a glucose target range compared to Tidepool Loop.<br>The DBLG2 software also adjusts the target |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | Pre-Meal Range:<br>Glucose Safety Limit (which can be set from 67-110 mg/dL) - 130 mg/dL<br><br>Workout Range:<br>the higher of 85 mg/dL or the Glucose Safety Limit (which can be set from 67-110 mg/dL) - 250 mg/dL | • Hypoglycemia threshold: 60 - 85 mg/dL (default value 70 mg/dL)<br><br>No target change required for meal management<br><br>Target during physical activities automatically adjusted by the DBLG2 application during the physical activity declaration.<br><br>Calculated amount of carbohydrates proposed to the patient to compensate for an existing or upcoming hypoglycemia.<br><br>Self-learning module that applies improvements to the patient's algorithm parameters, based on estimated glycemia history and insulin delivery quantities, from the patient's history. | based on activities declared by the user. Additionally, carbohydrates intake, and so the alarm system associated, is part of the risk control measures to avoid hypoglycemia episodes. Carbohydrates intakes confirmed by the patient as "taken" into DBLG2 application are then taken into account for the next iterations of the algorithm, for predicted glycemia evolution and future insulin delivery, each 5 min.<br>At last, DBLG2 software also includes a module for long term learning which impacts 3 situations : meals, correction boluses, and basal rate.<br><br>All combined, these DBLG2 software features and settings aim at avoiding excursions beyond the hypo/hyperglycemia thresholds, just like the predicate with its correction, pre-meal and workout ranges.<br><br>Both DBLG2 software and predicate devices have equivalent risks and mitigations to handle hyperglycemia and hypoglycemia episodes with their respective alarm systems and features. No new or modified risks. |
| Auto-populating bolus | | | Same |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| recommendation based on iCGM value:<br><br>In closed loop mode<br><br>In open loop mode | <br><br>Yes<br><br>No | <br><br>Yes<br><br>No | |
| Data List and Logging | Yes | Yes | Same |
| Daily Activity Records | Yes | Yes | Same |
| Average Data Display | Yes | Yes | Same |
| Password Required | Yes | Yes | Same |
| Performance Characteristics | | | |
| Bench Performance | Tidepool Loop performance was verified and validated through software verification testing including special controls, cybersecurity, wireless, and connected devices compatibility testing. | Diabeloop DBLG2 performance was verified and validated through software verification testing including special controls, cybersecurity, wireless, and connected devices compatibility testing. | Same |
| Clinical Performance | Tidepool Loop clinical performance is supported by representative 1,250 participants in a 15 months duration real-world, observational, single arm study of DIY Loop including both | Overall, the Diabeloop Software's clinical performance has been demonstrated through consistent results in 6 prospective clinical trials, collecting a total of 15,325 patient-weeks in adults and 1,594 | Equivalent.<br><br>Overall, the clinical data supporting the Diabeloop 510(k) submission were collected in the entire intended population |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | pediatric and adult participants. | patient-weeks in adolescents with T1D. Real-world studies involving large patient cohorts and post-hoc analyses have confirmed these findings and addressed specific questions, such as the applicability of clinical data collected with various software versions, unannounced meals, insulin types and requirements, specific operating modes, and customizable settings. | (in terms of age, sex, baseline HbA1c and previous treatment), in thousands of patients and with long-term follow-up, similar to the Tidepool study.<br>A summary of the strategy for demonstrating clinical performance is provided in section "Clinical Testing". |
| Risk Assessment | Tidepool Loop performed Risk Assessment including detailed hazard analysis based on ISO 14971. | Diabeloop DBLG2 performed Risk Assessment including detailed hazard analysis based on ISO 14971. | Same |
| Labeling | | | |
| Training | Tidepool Loop includes mandatory in-app learning and setup (user training) before the user can use Tidepool Loop. | All users must complete the training provided by a certified trainer before using DBLG2 for the first time (e-learning and face to face training). | Equivalent ; in both products, training is a mandatory step of the process ; the difference remains in the media used.<br>Additionally, training on features associated with the DBLG2 software and the impact on safety and effectiveness were evaluated through Human Factors testing and found to be safe and effective for the intended users, uses, and use environments. |
| User Guide | Tidepool Loop electronic User Guide also includes all special controls, clinical | DBLG2 application User Guide also includes all special controls, clinical | Same |

| Characteristic | Tidepool Loop (K203689) | Diabeloop DBLG2 (this submission, submission Number: Q182031/S006) | Analysis |
|---|---|---|---|
| | performance information and other information needed per cybersecurity and interoperability requirements. | performance information and other information needed per cybersecurity and interoperability requirements. | |

# 8. Standards Compliance

DBLG2 complies with the following standards as documented in the applicable reports and documents provided in this 510(k) submission.

## 8.1. US Regulation

| US Regulation number | US Regulation name |
|---|---|
| 21 CFR Part 801 | Labeling requirements |
| 21 CFR Part 803 | Medical Device Reporting (MDR) |
| 21 CFR Part 806 | Medical Devices; Reports of Corrections and Removals |
| 21 CFR Part 807 | Establishment registration & medical device listing |
| 21 CFR Part 812 | Investigational Device Exemptions |
| 21 CFR Part 820 | Quality System (QS) regulation |
| 21 CFR Part 822 | Postmarket Surveillance |
| 21 CFR Part 830 | Unique Device Identification |
| 21 CFR 862.1356 | Interoperable automated glycemic controller special controls |
| 21 CFR Part 11 | Electronic records; Electronic signatures |

## 8.2. Standards

| Standard number | Standard name | Standard version | FDA recognition number |
|---|---|---|---|
| EN ISO 20417 + A11 | Medical devices — Information to be provided by the manufacturer | 2021 | 5-135 |
| ISO 14155 | Clinical investigation on medical devices for human subjects - Good clinical practice | 2020 | 2-282 |
| ISO 14971 | Medical Devices - Application of risk management to medical devices | 2019 + 2021 | 5-125 |
| ISO 15223-1 | Medical devices - symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements | 2021 | 5-134 |
| IEC 62304 + A1 | Medical device software - software life-cycle processes | 2006 + 2015 | 13-79 |
| IEC 62366-1+A1 | Medical devices. Application of usability engineering to medical devices | 2015+2020 | 5-129 |
| IEC 81001-5-1:2021 | Health software and health IT systems safety, | 2021 | 13-122 |

| | | | |
|---|---|---|---|
| | effectiveness and security | | |

# 9. Non-Clinical Performance Testing

The information presented in this 510(k) submission demonstrates the safety and effectiveness of Diabeloop DBLG2 with compatible ACE pump and iCGM devices.

## 9.1. Risk Management

Risk management was performed and documented in accordance with ISO 14971:2019+A11:2021. A comprehensive hazard analysis was provided for this device, in which design inputs and outputs, risks, and risk mitigations for software and interoperable hardware components associated with the safe and effective functioning of the device were reviewed. The hazard analysis provided in this submission accounted for the unique design elements, intended use, and risks of the Diabeloop DBLG2 iAGC.

## 9.2. Human Factors Validation

A human factors (HF) validation study was conducted in accordance with ANSI/AAMI/IEC 62366-1:2015. The study was conducted to confirm that intended users can safely and effectively use the Diabeloop DBLG2 Mobile Application. The final device design was evaluated in a summative study performed in Cincinnati, Ohio, with 34 participants representative interacting with the device in a simulated use environment. Results of the study demonstrated that the product has been found to be safe and effective for the intended users, uses, and use environments.

## 9.3. Software Verification and Validation

Software verification and validation testing was performed in accordance with IEC 62304:2006 + A1:2015 and with FDA guidance, General Principles of Software Validation, issued January 11, 2002. DBLG2 application was installed on compatible Android devices, and tested extensively using manual tests and automated simulation tests.
Testing was performed to ensure that DBLG2's functions through compatible host devices incorporating wireless technologies (BLE) performed as designed and intended.

## 9.4. Interoperability

DBLG2 is an interoperable automated glycemic controller (iAGC) as defined under 21 CFR § 862.1356. As an interoperable device, DBLG2 is intended to be integrated with multiple third-party ACE Pumps and iCGM devices. The list of integrated devices that are compatible with Diabeloop System is expected to grow over time.

### 9.5. Cybersecurity

A cybersecurity analysis was performed for Diabeloop DBLG2 using FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. DBLG2 provided a software bill of materials, which provided details on all software used in the device. This included all manufacturer-developed, commercially licensed, open source, and off-the-shelf software components, along with an identification of the hardware runtime environment in which each resides, with relevant version and/or model information, as well as details on whether each component was actively supported by its manufacturer or legacy licensed. In addition, results of internal testing and third-party penetration testing, using existing devices and configurations, were provided.

## 10. Clinical Testing

The clinical development strategy to demonstrate the safety and effectiveness of the Diabeloop Software incorporated prospective clinical trials conducted according to ISO:14155 and ICH E6 Good Clinical Practices, along with real-world data to address specific questions.

Collectively, the results of multiple prospective clinical trials evaluating the performance of the Diabeloop software demonstrate its safety and effectiveness over the entire intended population (in terms of age, sex, baseline glucose control, and previous treatment), in real-world settings and with long-term follow-up. With a total of 15,325 effective patient-weeks collected in adults and 1,594 in adolescents with T1D, this clinical data supports substantial equivalence to the predicate device which presented 2,080 adult patient-weeks and 2,470 pediatric (6-18 years) patient-weeks of device exposure. The results of the prospective clinical trials conducted by Diabeloop highlight various improvements in glycemic outcomes, including Time in Range (TIR) 70-180 mg/dL, time in hypoglycemia, time in hyperglycemia, mean Continuous Glucose Monitoring (CGM) value, HbA1c, and occurrence of severe metabolic episodes. High satisfaction was also reported in the various studies. Additionally, the real-world data presented addresses specific questions, such as the applicability of clinical data collected with various software versions and the device's performance when using specific operating modes and customizable settings, with different types of insulin, for patients with high total daily insulin doses and varied meal declaration habits.

## 11. Conclusion

DBLG2 software is substantially equivalent to the predicate Tidepool Loop cleared in K203689. The differences, summarized in this submission, do not raise different questions of safety or effectiveness. The performance of the device is supported by Diabeloop's design control process which included non-clinical testing and risk management activities.
The non-clinical and clinical performance data described above supports also the determination of substantial equivalence. Human factors and clinical validation demonstrated that Diabeloop software performed as designed and intended for the intended users, uses, and use environments.
The device meets all Special Controls for this product type as required by 21 CFR 862.1356 for interoperable Automated Glycemic Controllers, Product Code QJI.

# 12. Document history

| DA # | Version | Description | Effective date | Author |
|---|---|---|---|---|
| DA 00198 | 0 | Creation of the document | See Qualios signature page | Alexandre VICENTE |
| DA 00271 | 1 | Context : next to FDA deficiencies associated with K251152<br>Update of sections :<br>- §Device description<br>- §Indication for Use<br>- §Comparison to Predicate Device<br>- §Clinical Testing | See Qualios signature page | Alexandre VICENTE |
| DA 00281 | 2 | Context : next to FDA deficiencies associated with K251152.S001.IR#3<br>Update of sections Indication for use and Comparison to Predicate Device | See Qualios signature page | Franck FOUREL |
| DA 00281 | 3 | Context : next to FDA deficiencies associated with K251152.S001.IR#4a<br>Update of section Clinical Testing | See Qualios signature page | Benjamin CHATEL |
| DA 00281 | 4 | Context: next to FDA deficiencies associated with K251152.S001.IR#3<br>Update of contraindication - replace “8U” by “8 units” | Available on Qualios | Alexandre VICENTE |
| DA 00281 | 5 | Update of contact phone<br>Removal of “company confidential” in the footer | Available on Qualios | Erik HUNEKER |