



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K262599

B Applicant

Biolinq Incorporated

C Proprietary and Established Names

Biolinq Shine Autonomous Time-in-Range Microsensor

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SFU	Class II	21 CFR 862.1359 Glucose range monitoring system	Clinical Chemistry

E Purpose for Submission:

Modification from Prescription Use Only to Over The Counter use

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Biolinq Shine Autonomous Time-in-Range Microsensor consists of a continuous intradermal glucose sensor with a color-changing indicator light. It is intended to measure, record, and analyze physiologic data using an array of microsensors combined with an accelerometer and ambient light sensor. The qualitative display communicates real-time changes in glucose levels in persons 22 years or older not on insulin. The device may be used to aid in the management of a disease or condition related to glycemic control. An app provides more granular glucose information. It analyzes and correlates this glucose information with meals, rest, and activity levels. Use of the glucose and activity information is designed to facilitate acute behavior and lifestyle modifications. Interpretation of device readings should be based on glucose and activity

trends and patterns. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- Remove the sensor before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, high-frequency electrical heat (diathermy) treatment, X-ray machines, and Advanced Imaging Technology (AIT) body scanners. The magnetic fields and radiation could damage the device components.
- This device is not intended for pregnant women, people on dialysis, critically ill patients, or persons under 22 years of age.
- Do not use for hypoglycemia awareness. The sensor must not be used in persons with Type 1 Diabetes, those at significant risk of severe hypoglycemia, those taking any form of insulin, or with Automated Insulin Delivery (AID) Systems. The sensor does not provide glucose information below 70 mg/dL and does not provide alerts or alarms.
- Do not use if you have significant color blindness, profound visual impairment that cannot be corrected, monochromacy (complete colorblindness), or inability to see small objects as the device uses small colored lights.
- Do not use while taking hydroxyurea (used for cancer and sickle cell anemia treatment) as it causes inaccurate readings.
- Do not use during or shortly after medical tests involving drinking xylose (D-Xylose absorption test).
- Acetaminophen may falsely raise sensor readings (Acetaminophen can be found in many medications, including Tylenol®, Excedrin®, and cold medicines). Use a fingerstick blood glucose meter if sensor readings don't match symptoms when taking acetaminophen.
- Environmental and activity limitations: Do not use for SCUBA diving, above 10,500 feet (3,200 meters) altitude, or outside temperature range of 50-107°F (10-42°C).
- Water resistance: Can be submerged up to 6 feet (2 meters) for up to 30 minutes maximum.
- For airport security, use hand-wanding, pat-downs, or metal detectors instead of AIT body scanners.
- Wear on inner forearm only, avoiding areas too close to elbow or wrist. Do not place on irritated or damaged skin, scarring, cuts, burns, wounds, or other skin damage.
- Single use only - cannot be reused or re-applied if it falls off.

III Device Description

BiolinQ Shine Autonomous Time-in-Range Microsensor is an autonomous intradermal time-in range microarray sensor intended to measure glucose in people not using insulin. The wearable consists of an array of seven microelectrodes ("microsensors") that reside in the papillary dermis to continuously measure interstitial fluid glucose. The device is designed to be worn on the volar forearm (inner surface of the forearm) for placement in the user's field of vision. It continuously measures glucose levels (when concentrations are within 70-400 mg/dL) and stores data for up to five days.

The device includes a built-in user interface that provides real-time feedback through LED lights visible directly on the wearable. The lights blink throughout the wear period. A blue LED light

indicates glucose levels in the range of 70 to 180 mg/dL. A yellow LED light indicates glucose levels 181-400 mg/dL, and a red LED light indicates glucose levels below 70 mg/dL. Additional features on the wearable include concurrent flashing blue in the top and bottom hemisphere of the wearable to reflect when the user's glucose is rising more rapidly and directionally headed to the yellow zone, and the wearable flashing increases in intensity when the user's glucose is above 400 mg/dL. If the algorithm determines glucose levels cannot be provided, the wearable flashes white light in the upper hemisphere as a system error notification. When the device reaches end of use life, it displays a purple light to indicate the sensor should be replaced.

After application, the device starts operating automatically without user interaction and begins providing continuous glucose measurements in two hours without requiring external reference fingerstick blood glucose values (autocalibration). Combined with the integrated lights and its visible wear location, it can be used as a standalone device not requiring a separate display device or app. An app is available, but not required, for additional context and behavioral insights about glucose time-in-range related to daily activities. The device is applied using a single-use applicator and includes additional features such as ambient light sensing for LED brightness adjustment and accelerometer-based activity tracking.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Biolinq Shine Autonomous Time-in-Range Microsensor

B Predicate 510(k) Number(s):

DEN240080

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K262599</u>	<u>DEN240080</u>
Device Trade Name	Biolinq Shine Autonomous Time-in-Range Microsensor	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Automatically measure glucose in bodily fluids continuously for a specified period of time.	Same
General Device Characteristic Differences		
Availability to user	Over the counter	Prescription use only

V Standards/Guidance Documents Referenced:

ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices. Recognition Number: 5-125

ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]. Recognition Number: 13-79

AAMI TIR57:2016 Principles for medical device security - Risk management. Recognition Number: 13-83

AAMI TIR97:2019 Principles for medical device security - Postmarket risk management for device manufacturers. Recognition Number: 13-112

ANSI AAMI IEC TIR 80001-2-2:2012 Application of risk management for IT Networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls. Recognition Number: 13-42

ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1. Recognition Number: 5-129

VI Performance Characteristics:

A. Non-Clinical Performance

The proposed OTC indication was supported through human factors evaluations and labeling modifications. The human factors evaluation and labeling modifications were reviewed and found to be adequate in supporting OTC use.

B. Clinical Studies:

No new clinical studies were submitted. Clinical data was provided in DEN240080 and is still applicable to this device.

C. Other Supportive Device Performance Characteristics Data

None.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.