



**EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
Biolinq Shine Autonomous Time-in-Range Microsensor
DECISION SUMMARY**

I Background Information:

A De Novo Number

DEN240080

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

II Submission/Device Overview:

A Purpose for Submission:

De Novo request for evaluation of automatic class III designation for the Biolinq Shine Autonomous Time-in-Range Microsensor.

B Measurand:

Glucose in interstitial fluid

C Type of Test:

Semi-Quantitative, amperometric assay (glucose oxidase)

III 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 to aid in the management of a disease or condition related to glycemic control in persons 22 years or older not on insulin. 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):

Rx - For Prescription Use Only

- 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.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A 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.

B Principle of Operation

BiolinQ Shine Autonomous Time-in-Range Microsensor uses an array of intradermal electrochemical sensors to monitor glucose levels in the interstitial fluid (ISF). It also uses an accelerometer and ambient light sensor to monitor activity and rest. The wearable is held in place with an adhesive patch and serves as the primary glucose display. The sensor uses a glucose oxidase enzyme to catalyze the oxidation of glucose and transfer electrons to an electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the ISF. The device converts the electrical current signal to glucose, which is displayed directly on the device as qualitative glucose ranges. The system also communicates glucose, ambient light, and accelerometer data to a mobile app that displays glucose information, activity, and sleep duration.

C Instrument Description Information

1. Instrument Name:

BiolinQ Shine Autonomous Time-in-Range Microsensor

2. Specimen Identification:

Not applicable.

3. Specimen Sampling and Handling:

Not applicable.

4. Calibration:

The device is factory calibrated and does not accept user calibration.

5. Quality Control:

Not applicable

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this submission, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Standards/Guidance Documents Referenced:

1. ISO 13485, Medical devices. Quality management systems. Requirements for regulatory purposes

2. ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices
3. ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
4. ISO 10993-2 Third edition 2022-11, Biological Evaluation of medical devices - Part 2: Animal welfare requirements
5. ISO 10993-3 Third edition 2014-10-1, Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
6. ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7. ISO 10993-6 Third edition 2016-12-01, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
8. ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
9. ISO 10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
10. ISO 10993-12 Fifth edition 2021-01, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
11. ISO 10993-17 First edition 2002-12-01, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
12. ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
13. ISO 11137-1 First edition 2006-04-15, Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine control
14. ISO 11137-2 Third edition 2013-06 [Including AMD1:2022], Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
15. ISO 11737-1 Third edition 2018-01 [Including AMD1:2021], Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms.
16. ISO 11737-2 Third edition 2019-12, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation.
17. ISO 13004, Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmax
18. ANSI AAMI ST72:2019, Bacterial endotoxins - Test methods routine monitoring and alternatives to batch testing
19. ANSI AAMI ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems
20. ASTM F2825-18, Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
21. ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems
22. IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

23. ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021], Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard
24. IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard
25. IEC 60601-1-11, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard
26. ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text), Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
27. ANSI AAMI TIR69:2017/(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices
28. RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment
29. ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
30. ANSI AAMI TIR57:2016, Principles for medical device security - Risk management
31. ANSI AAMI TIR97:2019, Principles for medical device security - Postmarket risk management for device manufacturers
32. 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.
33. CLSI EP07 3rd Edition, Interference Testing in Clinical Chemistry
34. CLSI EP37 1st Edition, Supplemental Tables for Interference Testing in Clinical Chemistry

VI Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

Clinical performance of the Biolinq Shine Autonomous Time-in-Range Microsensor was evaluated in a clinical study described in Section C(3) below. A subset of subjects wore two devices at the same time. Precision was evaluated by comparing the glucose ranges indicated the two devices worn by the same subject on the forearm.

wearable

Performance data from all subjects with two (2) wearables where each wearable provided at least one glucose measurement with a concurrent time stamp (less than 2.5 minutes from the other wearable) was evaluated for precision analysis. Sixty-eight (68) out of the 77 subjects who received two wearables were included in this analysis. The subject with the primary wearable that was turned off by the algorithm after not displaying any glucose data and the sensors not meeting the manufacturing specs were excluded from this analysis. A total of

77,311 matched pairs were included in the analysis. Precision analysis was performed using contingency tables to assess concordance between the color displays of paired devices for the four glucose display categories (Red, Blue, Yellow, Yellow fast flashing) on the wearable, as well as the six glucose ranges in the mobile app. Concurrence Analysis for

Wearable Display Ranges

Primary (mg/dL)	Secondary (mg/dL)			
	< 70	70-180	181-400	> 400
< 70	916 / 1,727 (53.0%)	806 / 1,727 (46.7%)	5 / 1,727 (0.3%)	0 / 1,727 (0.0%)
70-180	772 / 52,144 (1.5%)	47,339 / 52,144 (90.8%)	4,033 / 52,144 (7.7%)	0 / 52,144 (0.0%)
181-400	25 / 25,972 (0.1%)	5,670 / 25,972 (21.8%)	20,269 / 25,972 (78.0%)	8 / 25,972 (0.0%)
> 400	0 / 42 (0.0%)	0 / 42 (0.0%)	42 / 42 (100.0%)	0 / 42 (0.0%)

Concurrence Analysis for Mobile App Display Ranges

Primary (mg/dL)	Secondary (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70	916 / 1,727 (53.0%)	787 / 1,727 (45.6%)	19 / 1,727 (1.1%)	5 / 1,727 (0.3%)	0 / 1,727 (0.0%)	0 / 1,727 (0.0%)
70-125	731 / 24,985 (2.9%)	19,837 / 24,985 (79.4%)	4,172 / 24,985 (16.7%)	245 / 24,985 (1.0%)	0 / 24,985 (0.0%)	0 / 24,985 (0.0%)
126-180	41 / 27,159 (0.2%)	5672 / 27,159 (20.9%)	17,658 / 27,159 (65.0%)	3,768 / 27,159 (13.9%)	20 / 27,159 (0.1%)	0 / 27,159 (0.0%)
181-300	25 / 24,137 (0.1%)	483 / 24,137 (2.0%)	5,141 / 24,137 (21.3%)	17,739 / 24,137 (73.5%)	749 / 24,137 (3.1%)	0 / 24,137 (0.0%)
301-400	0 / 1,835 (0.0%)	14 / 1,835 (0.8%)	32 / 1,835 (1.7%)	957 / 1,835 (52.2%)	824 / 1,835 (44.9%)	8 / 1,835 (0.4%)
> 400	0 / 42 (0.0%)	0 / 42 (0.0%)	0 / 42 (0.0%)	0 / 42 (0.0%)	42 / 42 (100.0%)	0 / 42 (0.0%)

2. Linearity:

Not applicable. This is a semi-quantitative device.

3. Analytical Specificity/Interference:

For the BiolinQ Shine Autonomous Time-in-Range Microsensor, interference testing was conducted to evaluate potential interferents that could affect glucose range classification accuracy. Positive Bias was observed from three substances - acetaminophen, hydroxyurea and xylose in bench testing.

Acetaminophen Clinical Interference Study

A single-site, single-arm, open-label observational study was conducted to evaluate acetaminophen interference. The study enrolled 31 subjects (with 30 completing device application) who received a single 1000 mg oral dose of acetaminophen. The study compared the device's glucose outputs to a laboratory blood glucose analyzer (YSI STAT Plus 2300) at the pre-dose baseline and every hour after acetaminophen ingestion for up to 6 hours.

Peak plasma concentration is expected 2-3 hours after oral acetaminophen ingestion.

Agreement of the semi-quantitative outputs from the Biolinq Shine Autonomous Time-in-Range Microsensor with the comparator method (CM) is presented below.

Wearable Agreement with CM after Acetaminophen Administration

Time	n	Biolinq In Agreement with CM (%)	Biolinq In Higher Range than CM (%)	Biolinq In Lower Range than CM (%)
Pre-dose	247	81.0%	13.4%	5.7%
1 h Post-dose	117	74.4%	20.5%	5.1%
2 h Post-dose	111	79.3%	14.4%	6.3%
3 h Post-dose	110	83.6%	13.6%	2.7%
4 h Post-dose	114	76.3%	18.4%	5.3%
5 h Post-dose	113	75.2%	15.9%	8.8%
6 h Post-dose	113	79.6%	10.6%	9.7%

Mobile App Agreement with CM after Acetaminophen Administration

Time	n	Biolinq In Agreement with CM (%)	Biolinq In Higher Range than CM (%)	Biolinq In Lower Range than CM (%)
Pre-dose	247	67.2%	17.8%	15.0%
1 h Post-dose	117	59.0%	27.4%	13.7%
2 h Post-dose	111	64.0%	23.4%	12.6%
3 h Post-dose	110	60.9%	24.5%	14.5%
4 h Post-dose	114	54.4%	31.6%	14.0%
5 h Post-dose	113	61.9%	22.1%	15.9%
6 h Post-dose	113	64.6%	14.2%	21.2%

In the acetaminophen clinical interference study, while the majority of glucose ranges indicated on the wearable and mobile app are consistent with the ranges from the comparator method, there is a greater propensity for the discordant wearable to be in a higher range than the comparator method. Based on the findings from the interference studies, the following statements are included in device labeling:

- *Acetaminophen*: "Consider the effect of acetaminophen. Taking acetaminophen may falsely raise the sensor's readings and cause it to show a higher glucose level than your actual level. Acetaminophen can be found in many medications, including Tylenol®, Excedrin®, and cold medicines. Since this device is intended to provide lifestyle recommendations, not treatment decisions, rely on a fingerstick blood glucose meter if the sensor's output does not match your symptoms or expectations when taking acetaminophen."
- *Hydroxyurea*: "Hydroxyurea, even at standard doses, will interfere with the sensor's ability to measure glucose, and it will measure glucose higher than the actual glucose in your body."
- *Xylose*: "Do not use this device during or shortly after a medical test that involves drinking xylose (sometimes called a 'D-Xylose absorption test'). Xylose in the body can interfere with glucose results. Ask your doctor how long you should wait after such a test before checking your glucose. This device has not been evaluated for use in people with rare medical conditions that affect xylose metabolism."

4. Assay Reportable Range:

The device measures glucose within the range of 70-400 mg/dL and ranges are displayed through color-coded LED lights on the wearable:

- Red LED light: <70 mg/dL
- Blue LED light: 70-180 mg/dL
 - Single blue light: In range
 - Concurrent flashing blue (top and bottom): In range and rising rapidly (>2 mg/dL/minute)
- Yellow LED light: 181-400 mg/dL
- Yellow LED with increased flashing intensity: >400 mg/dL (above measuring range)

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Biolinq Shine Autonomous Time-in-Range Microsensor has a storage shelf-life of 6 months that was evaluated at room temperature storage conditions between 36-86°F (2-30°C) and 10-90% humidity.

6. Detection Limit:

If a glucose measurement is less than 70 mg/dL, the result is displayed as a red LED light on the wearable. If the glucose measurement exceeds 400 mg/dL, the result is displayed as a fast-flashing yellow LED on the wearable. Data supporting this claimed range was submitted through the pivotal clinical study described in section VI.C.3.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison:

Not applicable. Accuracy was determined by comparing device values to an FDA cleared laboratory grade glucose analyzer (Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer) and referred to as the “comparator method” in Section VI.C.3 below.

2. Matrix Comparison:

Not applicable. The device only detects glucose in interstitial fluid.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

One pivotal clinical study was conducted at 6 centers across the United States from February 29, 2024 to June 10, 2024. The study enrolled 247 adult participants (22 years and older) with diabetes mellitus and 202 subjects wore Biolinq Shine Autonomous Time-in-Range Microsensor, including 66.8% Type 1 diabetes (Type 1 diabetes subjects were included in the clinical study to obtain sufficient data across the glucose display range.), 20.3% Type 2 diabetes on intensive insulin therapy, 5.9% Type 2 diabetes on basal insulin only, and 6.9% Type 2 diabetes not on insulin. About 90% of the subjects have been diagnosed with diabetes mellitus (DM) for more than 10 years. Below shows the demographic information of this study.

Demographics Summary Statistics

Demographic	Mean $\pm$ SD (Median) or n (%)
Age (years)	49.4 $\pm$ 15.6 (52.6)
Female	96 (47.5%)
Hispanic/Latino	49 (24.3%)
Race*	
White or Caucasian	166 (84.3%)
Black or African American	16 (8.1%)
Asian	12 (6.1%)
Other	9 (4.6%)
Fitzpatrick Skin Type	
Type I	2 (1.0%)
Type II	46 (22.8%)
Type III	69 (34.2%)
Type IV	68 (33.7%)
Type V	15 (7.4%)
Type VI	2 (1.0%)
Years diagnosed with DM (years)	
DM diagnosed (< 1.0)	1 (0.5%)
DM diagnosed (1.0-2.9)	4 (2.0%)
DM diagnosed (3.0-5.9)	5 (2.5%)
DM diagnosed (6.0-10.0)	10 (5.0%)
DM diagnosed (> 10)	182 (90.1%)
Height (in)	67.2 $\pm$ 4.2 (67.1)
Weight (lbs.)	198.9 $\pm$ 47.4 (192.4)
BMI (kg/m²)	30.9 $\pm$ 7.2 (30.4)
BMI Category (kg/m²)	
Underweight (<18.5)	1 (0.5%)
Normal (18.5-24.9)	36 (17.8%)
Overweight (25.0-29.9)	60 (29.7%)
Obese Class I (30.0-34.9)	62 (30.7%)
Obese Class II (35.0-39.9)	24 (11.9%)
Obese Class III ($\geq$ 40.0)	19 (9.4%)

N = 197 total subjects reported their race. N = 202 total subjects for all other Demographics

Participants wore either one or two BiolinQ Shine Autonomous Time-in-Range Microsensors for up to 5 days (120 hours). A subset of participants (n=77, 38.1%) wore two wearables for precision analysis to compare variability of readings between sensors. All participants wore their BiolinQ Shine Autonomous Time-in-Range Microsensor system(s) on the volar forearm. Clinic sessions took place on Day 1 (0-25 hours), Day 3 (47-73 hours), and/or Day 5 (95-120 hours).

Glucose levels of study participants were manipulated per protocol to raise or lower blood glucose levels to assess performance over the device's measuring range (40-400 mg/dL). Subjects participated in two or three clinic sessions (Day 1: 11.5 hours, Days 3 & 5: 10 hours each) compared to a comparator method (CM).

The device was blinded during the clinical study. Accuracy of the device was evaluated by comparing device glucose outputs obtained through post-hoc analysis to the corresponding venous blood glucose samples measured on the CM. Blood draws were performed every 15 minutes during in-clinic sessions.

Wearable Display and CM Concurrence Rate (Overall)

Biolineq (mg/dL)	CM (mg/dL)			
	< 70	70-180	181-400	> 400
<70 (n=674)	73.9%	26.1%	0.0%	0.0%
70-180 (n=7,904)	6.7%	79.8%	13.5%	0.0%
181-400 (n=5,964)	0.0%	12.8%	86.2%	1.0%
> 400 (n=14)	0.0%	0.0%	21.4%	78.6%

Mobile App Display and CM Concurrence Rate (Overall)

Biolineq (mg/dL)	CM (mg/dL)					
	<70	70-125	126-180	181-300	301-400	>400
<70 (n=674)	73.9%	26.1%	0.0%	0.0%	0.0%	0.0%
70-125 (n=4,093)	12.9%	66.9%	17.7%	2.4%	0.0%	0.0%
126-180 (n=3,811)	0.0%	17.7%	56.9%	24.8%	0.6%	0.0%
181-300 (n=5,197)	0.0%	0.3%	14.4%	70.9%	14.2%	0.1%
301-400 (n=767)	0.0%	0.0%	0.0%	20.7%	72.8%	6.5%
>400 (n=14)	0.0%	0.0%	0.0%	0.0%	21.4%	78.6%

Wearable Display and CM Concurrence Rate, Day 1

Biolineq (mg/dL)	CM (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=208)	53.8%	46.2%	0.0%	0.0%
70-180 (n=2,890)	6.7%	80.3%	13.0%	0.0%
181-400 (n=1,828)	0.0%	14.2%	84.4%	1.4%
> 400 (n=10)	0.0%	0.0%	30.0%	70.0%

Mobile App Display and CM Concurrence Rate, Day 1

Biolog (mg/dL)	CM (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=208)	53.8%	46.2%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,582)	12.2%	65.8%	19.4%	2.6%	0.0%	0.0%
126-180 (n=1,308)	0.0%	16.0%	58.5%	24.9%	0.6%	0.0%
181-300 (n=1,574)	0.0%	0.1%	16.5%	68.9%	14.6%	0.0%
301-400 (n=254)	0.0%	0.0%	0.0%	11.4%	78.7%	9.8%
> 400 (n=10)	0.0%	0.0%	0.0%	0.0%	30.0%	70.0%

Wearable Display and CM Concurrence Rate, Day 3

Biolog (mg/dL)	CM (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=264)	84.1%	15.9%	0.0%	0.0%
70-180 (n=2,430)	6.8%	79.0%	14.2%	0.0%
181-400 (n=2,300)	0.0%	14.2%	85.1%	0.7%
> 400 (n=0)	N/A	N/A	N/A	N/A

Mobile App Display and CM Concurrence Rate, Day 3

Biolog (mg/dL)	CM (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=264)	84.1%	15.9%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,230)	13.4%	65.7%	19.6%	1.3%	0.0%	0.0%
126-180 (n=1,200)	0.0%	18.6%	53.9%	27.3%	0.2%	0.0%
181-300 (n=2,078)	0.0%	0.7%	15.0%	70.1%	13.9%	0.3%
301-400 (n=222)	0.0%	0.0%	0.0%	26.1%	69.8%	4.1%
> 400 (n=0)	N/A	N/A	N/A	N/A	N/A	N/A

Wearable Display and CM Concurrence Rate, Day 5

Biolinq (mg/dL)	CM (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=202)	81.2%	18.8%	0.0%	0.0%
70-180 (n=2,584)	6.7%	80.0%	13.4%	0.0%
181-400 (n=1,836)	0.0%	9.8%	89.3%	0.9%
> 400 (n=4)	0.0%	0.0%	0.0%	100.0%

Mobile App Display and CM Concurrence Rate, Day 5

Biolinq (mg/dL)	CM (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=202)	81.2%	18.8%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,281)	13.4%	69.4%	13.8%	3.4%	0.0%	0.0%
126-180 (n=1,303)	0.0%	18.7%	58.1%	22.3%	0.8%	0.0%
181-300 (n=1,545)	0.0%	0.2%	11.5%	74.1%	14.2%	0.0%
301-400 (n=291)	0.0%	0.0%	0.0%	24.7%	69.8%	5.5%
> 400 (n=4)	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%

Assessment of Rate of Change (ROC)

Biolinq	CM (mg/dL/min)					
	> 2	(1,2]	[0,1]	[-1,0)	[-2,-1)	< -2
BLUE (70-180 mg/dL) and ROC is > 2 mg/dL/min (n=122)	52 (42.6%)	48 (39.3%)	17 (13.9%)	4 (3.3%)	1 (0.8%)	0 (0.0%)

Sensor life

Of the 190 primary wearables, one was shut off by the algorithm after not displaying any glucose data in the first 12-hour period. The survival rate was 84.7% for the intended duration of 5 days. The wearable survival rates by day are presented in the table below.

Biolinq Shine Autonomous Time-in-Range Microsensor Survival Rates

Wear Day	Number of Sensors	Survival Rate (%)
1	183	96.3%
2	178	93.7%
3	173	91.1%
4	169	88.9%
5	161	84.7%

Glucose Display Rate

The display rate of the wearable is the number of displayable glucose readings (red, blue, and yellow displays) available after post-processing divided by the number of expected glucose readings for the given wearable lifetime. The display rate summary statistics are shown on table below.

Biolinq Shine Autonomous Time-in-Range Microsensor Display Rate Summary Statistics

# of Operational Wearables	Mean $\pm$ SD (Median)	% of Wearables w/ $\geq$ 85% Display Rate
190	93.9 $\pm$ 13.7 (98.4)	88.9%

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Performance Characteristics Data:

Human Factors (HF)

Human factors and usability of the device were evaluated according to the FDA Guidance titled Applying Human Factors and Usability Engineering to Medical Devices, dated February 3, 2016, and IEC 60601-1-11:2015 titled Medical Electrical Equipment- General requirements for basic safety and essential performance. An analysis of hazards and risks was conducted to determine safety risks associated with use of the system. All critical tasks for which a use error could lead to high severity harm and the subject device user interface was evaluated. The data

demonstrated that use-related risks have been addressed and that further risk reduction is not necessary.

Software

Software regression testing was conducted in accordance with established specifications and documentation was provided as recommended by FDA Guidance "Content of Premarket Submissions for Device Software Functions." The test results met acceptance criteria and support that the subject product is acceptable for its intended use.

Cybersecurity

Cybersecurity verification and validation processes were conducted, and documentation was provided as recommended by FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." The cybersecurity processes included end-to-end encryption, secure authentication, and comprehensive penetration testing. The test results met acceptance criteria and support that the subject cybersecurity is acceptable.

Sterility and Package Integrity/Shipping Integrity

E-beam sterilization was validated to achieve a Sterility Assurance Level (SAL) of 10^{-6} with dose range of 20-35 kGy. Enhanced shelf-life validation was conducted per ASTM F2825-18, distribution simulation per ASTM D4169-23, and warehouse storage. All devices passed seal integrity testing per ASTM D3078 and found to be acceptable.

Biocompatibility

Biocompatibility testing was performed on the patient-contacting components using the guidelines described in ISO 10993-1. Testing included cytotoxicity, sensitization, irritation, acute systemic toxicity and pyrogenicity, subacute/subchronic toxicity, genotoxicity, implantation, and chronic toxicity and carcinogenicity assessments. A toxicological risk assessment was conducted according to ISO 10993-17:2023. The biocompatibility evaluation concluded that the device meets the requirements of ISO 10993-1:2018 and ISO 14971:2019.

Electromagnetic Compatibility and Wireless EMC testing was conducted according to IEC 60601-1-2:2014 including radiated emissions, electrostatic discharge immunity, radiated RF electromagnetic field immunity, and power frequency magnetic fields immunity. The system also demonstrated compliance with RTCA DO-160G Category M and Category T specifications. Wireless communication assessment determined the wireless function to be optional with negligible risk impact.

Electrical Safety The basic safety and essential performance was evaluated to IEC 60601-1:2020 and IEC 60601-1-11:2015. Essential performance criteria were revised and justified based on measurement accuracy and device intended use. Battery safety was evaluated for the sealed, non-rechargeable lithium manganese dioxide battery and found to be acceptable.

VII Proposed Labeling:

The labeling supports the decision to grant the De Novo request for this device.

VIII Benefit/Risk Assessment:

A Summary of the Assessment of Benefit:

The Biolinq Shine Autonomous Time-in-Range Microsensor, is intended to facilitate glucose monitoring in individuals ≥ 22 years old with a disease or condition related to glycemic control but not on insulin, which includes individuals with a diagnosis of Type 2 Diabetes (T2D) who do not rely on insulin for glycemic management. The device provides general awareness of glucose ranges to the user (i.e., semi-quantitative glucose data conveyed via colors, not discrete quantitative glucose values) and can additionally offer glucose insights/feedback to the user to encourage lifestyle modifications without requiring frequent fingerstick monitoring.

The frequency of glucose monitoring provided by the device is not feasible using traditional self-monitoring blood glucose (SMBG) meters that only provide information about discrete intermittent blood glucose ranges and thus would require excessive SMBG measurements throughout the day and night, which is both burdensome and unrealistic for users. Although no discrete glucose value is provided by the device on either the wearable or the mobile app like a conventional quantitative CGM, the device primarily informs the user if they are in a euglycemic range and how their glucose ranges change in response to food intake, activity, or consistency with their prescribed non-insulin pharmacologic regimen, etc. Additionally, although only available in the optional app, the user can receive encouraging feedback when in the euglycemic glucose range and/or behavioral modification suggestions. This device would be especially helpful for individuals who have limited number literacy or who find SMBG monitoring too painful, burdensome, and/or stigmatized. These individuals currently manage their diabetes with minimal to no objective glucose data outside of a quarterly or biannual HbA1c level and thus primarily rely on subjective assessment of their glucose from day to day based on symptoms of hypoglycemia or hyperglycemia which are usually not apparent until the glucose ranges reach extremes.

Although to date, the benefit of when to initiate glucose monitoring with SMBG or with what frequency has not been sufficiently established to support formal recommendations by professional clinical societies for patients with T2D who are not treated with insulin, the use of a glucose range monitor offers the benefit of glucose range awareness to make clinically meaningful lifestyle changes as compared to individuals who perform minimal to no monitoring in other forms (i.e., SMBG or CGM) due to the higher burden of use from currently available quantitative devices. In addition, in users without a diabetes diagnosis prescribed the device by their health care provider (HCP) for various reasons (e.g., family history of T2D, overweight/obese BMI, Polycystic Ovarian Syndrome, use of other medications which may impact glucose levels, etc.) the high-level glucose data is sufficiently informative to promote discussion with their HCP if they note a significant proportion of their day is above the euglycemic range thus creating an opportunity for detection of hyperglycemia.

B Summary of the Assessment of Risk:

The risks associated with the use of a glucose range monitor are hypoglycemia or hyperglycemia related to use of inaccurate sensor glucose ranges to make treatment decisions. Because the

intended population for this device are patients who are otherwise likely to be monitoring glucose minimally if at all, it is likely that users who choose this device are not currently using SMBG with any regularity. Therefore, the lifestyle intervention decisions made based on the output of this device would carry similar to lower risk than when made without any glucose data at all. In addition, the device includes clear and consistent messaging about its limitations and guides the user to confirm glucose levels with an SMBG prior to acting on the glucose range provided by the device. In addition, the insights provided in the optional app are general, primarily encouraging when glucose is in target, and supportive when glucose strays from target, providing only high-level feedback about the positive impact of exercise, hydration, and assessing what meals may be a better choice in the future. Therefore, if used as intended, and by the intended use population who does not use insulin, the device effects are limited to low risk lifestyle interventions, and the risk of harm is unlikely.

When the device outputs are considered in the context of the intended use population and the intended purpose of the device to make the user generally aware if they are in optimal glucose levels or not, the device is sufficiently accurate for its intended purpose and with minimal risk of harm in the instances when less accurate. In the absence of appropriate mitigations, risks such as acting on inaccurate glucose information, false reassurance, or missed events could result in hypoglycemia or hyperglycemia. However, the application of special controls—including requirements for device performance verification and validation, certain labeling information along with validation of device usability and manufacturing quality controls—provide reasonable assurance that these risks are sufficiently mitigated.

C Patient Perspectives:

This submission did not include specific information on patient perspectives for this device.

D Summary of the Assessment of Benefit-Risk:

The clinical data for the Biolinq Shine Autonomous Time-in-Range Microsensor support that its accuracy is sufficient for the intended use population of persons ages 22 and above who range from people without diabetes to individuals with T2D who are not on insulin therapy. The probable benefit for all users of the awareness of changes in glucose ranges in response to food, exercise, and/or stress and the general awareness of whether glucose levels are in an optimal range for T2D outweighs the probable risk of inaccuracy given that the actionable changes these users could make are limited to lifestyle changes and unlikely to inflict. If used consistently and with assessment of patterns the probable benefits of the device to inform the user if they are maintaining a euglycemic glucose range levels and whether they have made changes to lower their glucose from a hyperglycemic to a euglycemic range as much as possible, and/or to lose weight outweigh the probable risks of hypoglycemia or hyperglycemia related to inaccuracy and which is unlikely to occur based on the device's output and the specific intended use population.

IX Conclusion:

The De Novo request is granted, and the device is classified under the following and subject to the special controls identified in the letter granting the De Novo request:

Product Code(s): SFU

Device Type: Glucose range monitoring system

Class: Class II (special controls)

Regulation: 21 CFR 862.1359