September 26, 2022

Bionime Corporation
% I Hsin Li
Regulatory Consultant
Symbiosis Consulting Ltd.
11F., No.95, Sec. 2, Nanjing E. Rd., Zhongshan Dist.,
Taipei, 10489
Taiwan

Re: K221062
Trade/Device Name: RIGHTEST Lancing Device GD500, GE Lancing Device, iGlucose Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: August 26, 2022
Received: August 26, 2022

Dear I Hsin Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221062

Device Name
BIONIME CORPORATION

Indications for Use *(Describe)*

RIGHTEST Lancing Device GD500

RIGHTEST Lancing Device GD500 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

GE Lancing Device

GE Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

iGlucose Lancing Device

iGlucose Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user.

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.

SECTION 5-510(k) SUMMARY

This 510 (K) summary is being submitted in accorndance with requirements of Title 21,CFR Section 807.92.

A. 510(k) NUMBER — K221062

B. DATE PREPARED — September 25th, 2022

C. SUBMITTER

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D. CONTACT PERSON

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Regulatory Consultant
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E. DEVICES

Proprietary Name:	RIGHTEST Lancing Device GD500
Common Name:	Multiple Use Blood Lancet For Single Patient Use Only
Product Code:	QRL
Regulation Number:	21 CFR 878.4850
Device Class:	Class II
Review Panel:	General & Plastic Surgery

Proprietary Name:	GE Lancing Device
Common Name:	Multiple Use Blood Lancet For Single Patient Use Only
Product Code:	QRL
Regulation Number:	21 CFR 878.4850
Device Class:	Class II
Review Panel:	General & Plastic Surgery

Proprietary Name:	iGlucose Lancing Device
Common Name:	Multiple Use Blood Lancet For Single Patient Use Only
Product Code:	QRL
Regulation Number:	21 CFR 878.4850
Device Class:	Class II
Review Panel:	General & Plastic Surgery

F. INDICATION(S) FOR USE

RIGHTEST Lancing Device GD500

RIGHTEST Lancing Device GD500 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

GE Lancing Device

GE Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

iGlucose Lancing Device

iGlucose Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user.

G.	PRIMARY PREDICATE DEVICE	Proprietary Name:	On Call Lancing Device
		Common Name:	Single Use Only Blood Lancet with An Integral Sharps Injury Prevention Feature
		Product Code:	FMK
		Regulation Number:	21 CFR 878.4850
		510(k) Number:	K113332
		510(k) Submitter:	ACON Laboratories Inc.
		Device Class:	Class II
		Review Panel:	General & Plastic Surgery
H.	SECONDARY PREDICATE DEVICE	Proprietary Name:	Genteel Lancing Device
		Common Name:	Single Use Only Blood Lancet with An Integral Sharps Injury Prevention Feature
		Product Code:	FMK
		Regulation Number:	21 CFR 878.4850
		Regulation Name:	Blood lancets
		510(k) Number:	K153670
		510(k) Submitter:	Genteel LLC
		Device Class:	Class II
		Review Panel:	General & Plastic Surgery

I. DEVICE DECRIPTION

RIGHTEST Lancing Device GD500/ GE Lancing Device/ iGlucose Lancing Device is a mechanical device holding and firing a single-use lancet linearly ahead to prick the skin to collect capillary whole blood from target sites. RIGHTEST Lancing Device GD500/ GE Lancing Device/ iGlucose Lancing Device can be adjusted for 7 levels of depth for a user collecting different amount of capillary blood.

J. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

RIGHTEST Lancing Device GD500, GE Lancing Device and iGlucose Lancing Device and predicate devices (K113332 and K113618) are:

1. Same “intended use/ indication(s) for use”
2. Same “Puncture device to obtain micro blood samples”
3. Same “Clear cap for testing alternative site”
4. Same “Lancet retracted after use to prevent sharp injure”
5. Same “Mechanical loading and firing function”
6. Same “Ejecting the used lancet Without touching the used disposable lancet”
7. Different “The depth of penetration”

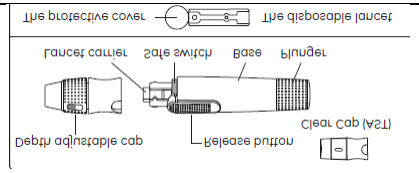
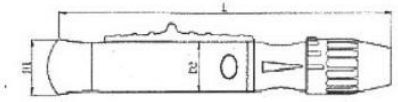
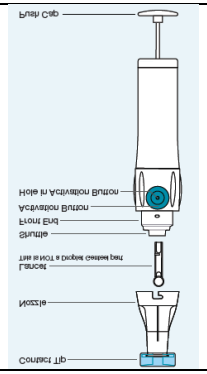
RIGHTEST Lancing Device GD500/GE Lancing Device/iGlucose Lancing Device and predicate devices (K113332 and K153670) are all the same intended use/ indication(s) for use, intended population, similar technical design and functions. The varying setting in the depth of penetration between RIGHTEST Lancing Device GD500/GE Lancing Device/iGlucose Lancing Device and predicate devices did not raise other concerns on safety and efficacy.

BIONIME CORPORATION concluded that RIGHTEST Lancing Device GD500/GE Lancing Device/iGlucose Lancing Device is substantially equivalent to the predicate devices On Call Lancing Device and the Genteel Lancing Device (K113332 and K153670).

K. A COMPARISON TABLE WITH PREDICATE DEVICES

Items	**Proposed Device** RIGHTEST Lancing Device GD500, GE Lancing Device and iGlucose Lancing Device	**Primary Predicate Device** On Call Lancing Device	**Secondary Predicate Device** Genteel Lancing Device	**Substantial Equivalence Comparison Assessment**
510(k) Number	TBD	K113332	K153670	N/A
Product Code	QRL	FMK	FMK	Different
Device Classification	Class II	Class II	Class II	Same
Intended Use/ Indication(s) for Use	RIGHTEST Lancing Device GD500 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device. GE Lancing Device is a reusable lancing device for the single user. It should be used with the	The On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.	The Genteel lancing device is used with disposable sterile lancets to draw capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. The Genteel lancing device is for Single Patient Use Only.	Same

Items	Proposed Device RIGHTEST Lancing Device GD500, GE Lancing Device and iGlucose Lancing Device	Primary Predicate Device On Call Lancing Device	Secondary Predicate Device Genteel Lancing Device	Substantial Equivalence Comparison Assessment
	proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device. iGlucose Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin			

Items	Proposed Device RIGHTEST Lancing Device GD500, GE Lancing Device and iGlucose Lancing Device	Primary Predicate Device On Call Lancing Device	Secondary Predicate Device Genteel Lancing Device	Substantial Equivalence Comparison Assessment
	penetration for each individual user.			
Puncture device to obtain micro blood samples	Yes	Yes	Yes	Same
Clear cap for testing alternative site	Yes	Yes	Yes	Same
Lancet retracted after use to prevent sharp injure	Yes	Yes	Yes	Same
Mechanical loading and firing function	Yes	Yes	Yes	Same
Ejecting the used lancet Without touching the used disposable lancet	Yes	Yes	Yes	Same
The depth of penetration	7 different depths The settings of penetration depths are 0.5 mm, 0.7 mm, 0.9 mm 1.1 mm, 1.3 mm, 1.5 mm and 1.7 mm.	6 different depths	six interchangeable contact tips	Different
OTC/Rx	OTC	OTC	OTC	Same
Design				Similar design

L.	SUMMARY OF PERFORMANCE DATA	The following performance data were provided to demonstrate the safety and efficacy: A. ISO 10993-5 In vitro Cytotoxicity B. ISO 10993-23 Skin Irritation C. ISO 10993-10 Skin Sensitization (Maximization Test) D. Functional tests were validated and completed. E. The cleaning and disinfections on the materials of device were evaluated and tested.
M.	SUBSTANTIAL EQUIVALENCE CONCLUSION	BIONIME CORPORATION concludes that the RIGHTEST Lancing Device GD500/GE Lancing Device/iGlucose Lancing Device is substantially equivalent to predicate devices in regard to indications for use, design, and technology, without raising any safety and efficacy risks or concerns.