April 19, 2023

YourBio Health, Inc.
Sean McCarthy
Director of Clinical and Regulatory Affairs
200 Boston Avenue
Suite 3700
Medford, Massachusetts 02155

Re: K223201
Trade/Device Name: TAP Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: October 13, 2022
Received: October 14, 2022

Dear Sean McCarthy:

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 and the limitations described below. 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.

The OHT4: Office of Surgical and Infection Control Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Precautions/Warnings/Contraindications section of the device's labeling in addition to being placed prominently immediately after any images or references to a collection tube:

1. This device is only for use with compatible collection tubes that are cleared for use with this device;

2. This device is not intended for use as a blood collection kit; and

3. This device is not intended for at-home collection or collection by lay-users.

Furthermore, the indication for use "The TAP Lancet is a single-use blood lancing device intended for producing microliter capillary whole blood samples. It does not collect or transport such samples." must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

David Krause -S

for Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
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)*
K223201

Device Name
TAP Lancet

Indications for Use *(Describe)*
The TAP Lancet is a single-use blood lancing device intended for producing microliter capillary whole blood samples. It does not collect or transport such samples.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
TAP Lancet®
K223201

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Owner/Applicant:	YourBio Health, Inc. 200 Boston Avenue Suite 3700 Medford, MA 02155 Telephone: (617) 547-7246 Establishment registration number: 3012853700
Official Correspondent	Sean T. McCarthy Director of Clinical and Regulatory Affairs YourBio Health, Inc. 200 Boston Avenue, Suite 3700 Medford, MA 02155 Telephone: (617) 435-6023 smccarthy@yourbiohealth.com
Date of Summary:	April 19, 2023
Device Trade Name:	TAP Lancet®
Common or Usual Name:	Blood lancet/ Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation Number:	21 CFR 878.4850
Device Class:	II
Product Code:	FMK
Panel:	General Surgery OHT4
Predicate Device:	Tasso+ (K221131)
Device Description:	The TAP Lancet is a single-use blood lancing device with an integral sharps injury prevention feature intended for producing microliter capillary whole blood samples. The TAP Lancet comprises a lancing module and a vacuum creation module which operate in an entirely mechanical fashion. The device uses a lancet and vacuum to initiate blood flow from the capillary bed in the upper arm. To use the device, the user removes that TAP Lancet from a sterile barrier package. Next, the user removes a protective liner from the bottom of the device to expose a layer of medical adhesive and places the device onto the desired specimen location on the upper arm. The medical adhesive seals to the skin and holds the device in place. When the TAP Lancet activation button is depressed, a lancet is deployed less than 1 mm deep into the skin to access capillaries. The lancet is then immediately and automatically retracted into a sharp shield. When the activation button

	is released, an internal vacuum bulb expands to generate and apply a gentle vacuum to the skin. The applied vacuum causes microliter quantities of capillary blood to emerge from the collection site.
Intended Use/Indications for Use:	The TAP Lancet is a single-use blood lancing device intended for producing microliter capillary whole blood samples. It does not collect or transport such samples.
Indications for Use Comparison	The indications for use of the candidate device are the same as the indications for use of the predicate device.
Technological Comparison	The technological characteristics of the candidate device are the same as the technological characteristics of the predicate device. The TAP Lancet blade length (1 mm) ensures that insertion risk has been mitigated. The blade length is shorter than the skin thickness (epidermal and dermal layers), which averages approximately 1-2 mm thick at the target collection site. Furthermore, the base of the blade bottoms out on the surface, preventing the blade tip from inserting any farther than its total length. The blade length was specifically designed to target capillary blood vessels such as arterioles and venules within the dermis layer of the skin, while minimizing invasiveness and preventing penetration beyond the subcutaneous layer. TAP Lancet incision size is 0.175 mm x 0.050 mm x 30 (maximum depth: 1mm). Predicate device incision size is Max Length: 5 mm and Max Depth: 2 mm.
Non-Clinical and/or Clinical Tests Summary & Conclusions	Non-clinical performance studies were conducted to confirm the overall functional specification testing of the device against its design specifications and intended use and to support substantial equivalence. The following testing was conducted: Package Integrity Testing: Package integrity testing was conducted to verify that the package formed a sealed sterile barrier. Package integrity testing included seal strength integrity evaluation via bubble leak testing (ASTM F2096), and seal peel strength evaluation (ASTM F88). Ship testing was conducted according to ISTA 2A with environmental conditioning. Shelf-life and Ship Testing: Shelf-life testing was conducted according to ASTM F1980. Biocompatibility Testing: The biocompatibility of the device materials was demonstrated via testing conducted in accordance with ISO 10993-1. Pyrogenicity Testing: The device was evaluated for pyrogenicity. The results demonstrated that the device is considered non-pyrogenic and meets the requirements of the Pyrogen Test, ISO 10993-11 guidelines. Usability Testing: The usability of the TAP Lancet with the instructions for use was

	evaluated in an actual-use study and is discussed in the clinical testing section of this submission. The device, in conjunction with the instructions for use, was found to be safe and effective for the intended use, and all residual risks were deemed acceptable for this type of device. An assessment of clinical performance data for the TAP Lancet successfully demonstrated its ability to produce blood samples from the upper arm of human subjects according to the device labeling. Subjects produced their blood samples following the TAP Lancet instructions for use. The devices had a total success rate of 95.0% and demonstrated that they performed as intended. The TAP Lancet met all functional requirements evaluated in non-clinical and clinical performance testing to demonstrate that the product is safe and effective for the intended use.