January 13, 2025

PrivaPath Diagnostics Ltd (dba LetsGetChecked)
Karen Walsh
Director of Manufacturing Quality and Regulatory
Unit 1, Northern Cross Business Park
North Road, Dublin 11
Dublin, D11XT26
Ireland

Re: K242680
Trade/Device Name: LetsGetChecked Impress
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: September 6, 2024
Received: December 10, 2024

Dear Karen Walsh:

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 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 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.

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

limitation 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 ImPress 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 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.

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,

HEATHER AGLER -S

Digitally signed by HEATHER AGLER -S
Date: 2025.01.13 17:06:24 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242680

Device Name

LetsGetChecked ImPress

Indications for Use *(Describe)*

The ImPress 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
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Office of Chief Information Officer
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"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 K242680 Prepared on: 2024-12-09

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	PrivaPath Diagnostics Ltd (dba LetsGetChecked)
Applicant Address	Unit 1, Northern Cross Business Park North Road, Dublin 11, D11XT26, Ireland Dublin D11XT26 Ireland
Applicant Contact Telephone	00353872442164
Applicant Contact	Ms. Karen Walsh
Applicant Contact Email	kwalsh@letsgetchecked.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	LetsGetChecked Impress
Common Name	Blood Lancets
Classification Name	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation Number	878. 4850
Product Code(s)	FMK

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223201	TAP Lancet	FMK

Device Description Summary 21 CFR 807.92(a)(4)

The LetsGetChecked ImPress is a single-use blood lancing tool equipped with an integral sharps injury prevention feature. It is intended for use by health care professionals in producing capillary whole blood samples from the upper arm.
To use the device, the user first removes the device tabs to expose the two internally contained lancets. The plastic strip liner is then removed, exposing a layer of medical adhesive. The device is then placed on the upper arm. Activation occurs when the device is compressed against the arm, causing two contact-activated lancets to puncture the skin. The lancets automatically retract to a safe position, preventing sharps injury and re-activation. The device operates solely through mechanical means.
During activation, the device generates a vacuum against the skin, which facilitates the emergence of microliter quantities of capillary blood from the puncture site.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The ImPress 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 21 CFR 807.92(a)(5)

Indications for use are the same as the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The indications for use of the candidate device has been found to be equivalent to the selected predicate device. Penetration of capillary blood vessels and application of vacuum to draw out whole blood samples is the underlying principle of both the subject and predicate devices.
At a high level, the subject and predicate device are both based on the same technological elements:

- Spring-loaded blade(s) to penetrate skin to reach capillary vessels.
- A retraction mechanism to withdraw the blades(s) from the skin to a location where it can no longer be accessed.
- A lock-out feature to permanently prevent the needles from being re-deployed.
- A mechanical means of manual activation.
- A means of sealing the device to the skin.
- A means of using spring force to create vacuum at the incision site.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical performance studies were conducted to confirm the device met specifications intended use, and to demonstrate substantial equivalence. The following testing was conducted:

> Shelf-life Testing per ASTM F1980
> Transport testing per D7386-16 and D4169-22
> Biocompatibility Testing per 10993-5 (Cytotoxicity)
> Usability Testing was performed to verify user comprehension of the instructions for use, validate the ability to produce blood samples from the upper arm when device is used according to the instructions for use, and to measure the devices ease of use and user satisfaction with the device.
> Accidental Drop Testing

The performance testing conducted as part of the 510(k) submission provides robust evidence that the candidate device meets or exceeds the safety, effectiveness, and performance standards of the predicate device.

The nonclinical testing conducted on the device demonstrate that it is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified as per section 21 CFR 807.92(a)(3). The testing results support the conclusion that the device meets all relevant safety and performance criteria, ensuring its suitability for its intended use.