January 20, 2023

GOSTAR Co., Ltd.
Pei-Fen Yang
President
2F, No.65, Wuquan 7nd Rd.
New Taipei City, Wugu District 248020
Taiwan

Re: K221419
Trade/Device Name: TD-5010 Lancing Device and TD-5084 Sterile Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: December 12, 2022
Received: December 14, 2022

Dear Pei-Fen Yang:

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,

Jessica Carr -S

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)*
K221419

Device Name
TD-5010 Lancing Device and TD-5084 Sterile Lancets

Indications for Use *(Describe)*
The TD-5010 Lancing Device and TD-5084 Sterile Lancets are intended to obtain capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The single-use TD-5084 Sterile Lancets are to be used with the reusable TD-5010 Lancing Device that is to be cleaned and disinfected between each use, and then the TD-5084 Sterile Lancets are to be disposed of.
For use only on a single patient in a home setting.
Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

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.

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K221419

510(k) Summary

In accordance with the requirements of 21 CFR 807.92, this summary is being provided to serve as the basis for the substantial equivalence determination.

1. 510(k) Owner Information

Correspondent	GOSTAR CO., LTD.
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Correspondent Contact	Pei-Fen Yang, Ph.D.
Title	President
Phone	+886-2-2298-1927
E-mail	ra.cert@gostarmed.com
Date Prepared	May 13, 2022

2. Candidate Device Information

Proprietary Name	TD-5010 Lancing Device and TD-5084 Sterile Lancets
Common Name	Lancing device; Lancets
Classification Product Code	QRL
Subsequent Product Code	QRK
510(k) Number	K221419
Review Panel	General & Plastic Surgery
Classification	2
Regulation Number	21 CFR 878.4850

3. Predicate Device Information

Manufacturer	Roche Diabetes Care, Inc.
Proprietary Name	Accu-Chek Softclix Blood Lancing System
Classification Product Code	QRL
Subsequent Product Code	QRK
510(k) Number	K214022
Review Panel	General & Plastic Surgery
Classification	2
Regulation Number	21 CFR 878.4850

4. Intended Use

The TD-5010 Lancing Device and TD-5084 Sterile Lancets are intended to obtain capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm.

The single-use TD-5084 Sterile Lancets are to be used with the reusable TD-5010 Lancing Device that is to be cleaned and disinfected between each use, and then the TD-5084 Sterile Lancets are to be disposed of.

For use only on a single patient in a home setting.

Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.

5. Device Description Summary

The **TD-5010 Lancing Device** uses compatible **TD-5084 Sterile Lancets** to obtain a drop of blood from a fingertip or alternative sites. The **TD-5010 Lancing Device** consists of two components:

(1) TD-5010 Lancing Device

(2) Alternative Site Testing (AST) Cap

6. Comparison to Predicate Device

6.1 Intended Use Comparison

The intended use of the candidate device is the same as the predicate device, including the testing sites and environment of use.

6.2 Technological Comparison

The TD-5010 Lancing Device uses compatible TD-5084 Sterile Lancets are substantially equivalent to the predicate device in terms of technological characteristics, including their intended use, function and design.

Table 1. Similarities Between the Predicate and Candidate Device

Characteristic	Predicate Device- K214022 Accu-Chek Softclix Blood Lancing System	Candidate Device- K221419 TD-5010 Lancing Device and TD- 5084 Sterile Lancets	Remark
Device Description	● The Accu-Chek Softclix Lancing Device uses compatible Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternative sites using the Accu-Chek Softclix Alternative Site Testing (AST) Cap. ● The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. ● This system is for use only on a single patient in a home setting. ● This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	● The TD-5010 Lancing Device uses compatible TD-5084 Sterile Lancets to obtain a drop of blood from a fingertip or alternative sites using the Alternative Site Testing (AST) Cap. ● The single-use TD-5084 Sterile Lancets are to be used with the reusable TD-5010 Lancing Device that is to be cleaned and disinfected between each use, and then the TD- 5084 Sterile Lancets are to be disposed of. ● For use only on a single patient in a home setting. Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	Identical
Intended Use	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	The TD-5010 Lancing Device and TD-5084 Sterile Lancets are intended to obtain capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The single-use TD-5084 Sterile Lancets are to be used with the reusable TD- 5010 Lancing Device that is to be cleaned and disinfected between each use, and then the TD-5084 Sterile Lancets are to be disposed of. For use only on a single patient in a home setting. Not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	Identical

Characteristic	Predicate Device- K214022 Accu-Chek Softclix Blood Lancing System	Candidate Device- K221419 TD-5010 Lancing Device and TD- 5084 Sterile Lancets	Remark
Mechanical Loading	Spring-driven	Spring-driven	Identical
Lancet Sterility	Gamma irradiation	Gamma irradiation	Identical
Number of Uses	Base (lancing device): multiple use Lancet: single use	TD-5010 Lancing Device: multiple use TD-5084 Sterile Lancets: single use	Identical
Anatomical Sites	Fingertip Ball of the hand (palm) Upper arm Lower arm (forearm)	Fingertip Ball of the hand (palm) Upper arm Lower arm (forearm)	Identical
Sharps Injury Prevention	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	The TD-5010 Lancing Device can be reset to operate only after the used lancet has been ejected which prevents multiple punctures with a used lancet. Ejection of used lancets is done by sliding the ejector.	Identical
Type of Use	Over the counter use	Over the counter use	Identical

Table 2. Differences Between the Predicate and Candidate Device

<table>
<tr><th>Characteristic</th><th>Predicate Device- K214022
Accu-Chek Softclix Blood Lancing System</th><th>Candidate Device- K221419
TD-5010 Lancing Device and
TD- 5084 Sterile Lancets</th><th>Remark</th></tr>
<tr><td>Appearance</td><td> 

Lancet:
 </td><td>TD-5010 Lancing Device and AST cap

TD-5084 Sterile Lancets
 </td><td>Difference 1</td></tr>
<tr><td>Puncture Depth and Exposed Needle Length</td><td>Not publicly available</td><td>
<table>
<tr><th>Segment</th><th>Puncture depth (mm)</th><th>Exposed needle length (mm)</th></tr>
<tr><td>Segment 1 (Minimum penetration depth)</td><td>0.8 ± 0.1</td><td>0.8 ± 0.1</td></tr>
<tr><td>Segment 2</td><td>1.0 ± 0.1</td><td>1.0 ± 0.1</td></tr>
<tr><td>Segment 3</td><td>1.2 ± 0.1</td><td>1.2 ± 0.1</td></tr>
<tr><td>Segment 4</td><td>1.4 ± 0.1</td><td>1.4 ± 0.1</td></tr>
<tr><td>Segment 5</td><td>1.6 ± 0.1</td><td>1.6 ± 0.1</td></tr>
<tr><td>Segment 6</td><td>1.8 ± 0.1</td><td>1.8 ± 0.1</td></tr>
<tr><td>AST Cap (Maximum penetration depth)</td><td>2.4 ± 0.1</td><td>2.4 ± 0.1</td></tr>
</table>
</td><td>Difference 2</td></tr>
<tr><td>Load</td><td>Load by pressing priming button when lancet is inserted</td><td>The TD-5084 Sterile Lancets can be loaded into TD-5010 lancing device by (1) installing the lancets into lancet holder of lancing device with enough loading force, or (2) inserting the lancets into lancet holder of lancing device then pulling the pulling cap of the TD-5010 lancing device with enough pulling force.</td><td>Difference 3</td></tr>
<tr><td>Needle</td><td>28G; beveled cut with 3 facets</td><td>30G; beveled cut with 3 facets</td><td>Difference 4</td></tr>
</table>

7. Discussion of Differences

7.1 Difference 1 (Appearance)

The user interfaces of candidate device include selector cap, AST cap, release button, pulling cap and ejector, the purposes of design are similar to predicate device. The mechanical performance test was performed to verify the lancets installation, loading, firing and ejection between candidate device and predicate device. All test results met acceptance criteria, which demonstrated that the different appearance design of candidate device could meet the same intended use as predicate device and didn't impact the safety and effectiveness.

The disinfection validation test and biocompatibility tests were performed to verify the housing materials of TD-5010 Lancing Device. The results demonstrated that the housing materials of TD-5010 Lancing Device would not affect the effectiveness of cleaning and disinfection, and biocompatibility.

The biocompatibility tests were performed to verify the materials of TD- 5084 Sterile Lancets. The results demonstrated that the materials of TD- 5084 Sterile Lancets would not affect the biocompatibility.

7.2 Difference 2 (Puncture Depth, Exposed Needle Length and Firmness Force)

The TD-5010 Lancing Device has 6 levels of puncture depth, which are adjustable by rotating the selector cap and installing the AST cap. The predicate device has 11 levels of puncture depth, which are adjustable by rotating the rotatable cap and AST cap.

The mechanical performance test was performed between candidate device and predicate device to verify the percussion of lancets for each puncture depth. The firmness force test was also performed in the accelerated and real-time aging tests of TD-5084 Sterile Lancets. According to the test results, puncture depths and exposed needle length of candidate device and predicate device both met its specifications, and the firmness force was within acceptance criteria in the accelerated and real-time aging tests. The puncture depth range and exposed needle length range of candidate device were similar to predicate device, and the needle of TD-5084 Sterile Lancets was verified to be firmly fixed in lancet housing at each time point of accelerated and real-time aging tests, which demonstrated that the safety and effectiveness of candidate device were substantially equivalent to predicate device.

7.3 Difference 3 (Load)

The TD-5084 Sterile Lancets can be loaded into TD-5010 Lancing Device by (1) installing the lancets into lancet holder of lancing device with enough loading force, or (2) inserting the lancets into lancet holder of lancing device then pulling the pulling cap of the TD-5010 lancing device with enough pulling force.

For predicate device, the lancets can be loaded into lancing device only by pressing the priming button.

The effectiveness of loading the lancets on lancing device was verified by measuring loading force and pulling force of TD-5010 Lancing Device. For predicate device, effectiveness of lancet loading was verified by measuring the pressing force of priming button.

All test results of lancets loading force on candidate device and predicate device met the acceptance criteria, which demonstrated that the safety and effectiveness of lancets loading (loading force and pulling force) of candidate device was substantially equivalent to predicate device.

7.4 Difference 4 (Needle)

The specification of TD-5084 Sterile Lancets (30G) is different from the lancets of predicate device (28G). In order to confirm the performance between the different lancet specifications, percussion of TD-5084 Sterile Lancets and predicate device was verified by measuring the puncture depth. The firmness force was also verified in the accelerated and real-time aging tests of TD-5084 Sterile Lancets.

All test results met the acceptance criteria, which demonstrated that puncture depths of both the TD-5084 Sterile Lancets (30G) and predicate device (28G) met the specifications, and the needle of TD-5084 Sterile Lancets (30G) was firmly fixed in lancet housing at each time point of accelerated and real-time aging tests. The safety and effectiveness of candidate device were substantially equivalent to predicate device.

8. Non-Clinical Testing Summary and Conclusions

8.1 Mechanical performance test

Mechanical functions were verified between candidate device and predicate device by bench tests.

8.1.1. Lancet Cap Twist Force and Pulling Force Test

To ensure the lancet cap of TD-5084 Sterile Lancets can be easily and safely removed by end user, the study verified the twist force and pulling force of removing the lancet cap between predicate device and candidate device. All test results met acceptance criteria which demonstrated that lancet cap of candidate device can be removed by end user smoothly and safely.

8.1.2. Firmness Force Test

The firmness force was measured by pulling up the needle from the lancet housing of candidate device to verify the needle was firmly fixed in lancet housing at each time point of accelerated and real-time aging tests. All test results met acceptance criteria, which demonstrated that the lancet needle of candidate device was firmly fixed in lancet housing during its claimed shelf life.

8.1.3. Drop testing

The appearance and performance of candidate device were verified after performing drop forces in order to ensure the candidate device met its intended use while conducting drop forces during operations. All test results met acceptance criteria, which demonstrated that lancing devices installed with lancets met its intended use after undergoing drop forces during operations.

8.1.4. Measure Penetration Depth

The different gap dimensions of lancing device will allow the needle on the lancet exposure in different lengths to reach different penetration depths for obtaining blood drops. The penetration depths were verified and compared between candidate device and predicate device. All results met acceptance criteria which demonstrated that the candidate device met its intended use and its claimed specifications.

8.1.5. Loading force and pulling force

The TD-5084 Sterile Lancets can be loaded into TD-5010 Lancing Device by: (1) installing the lancets into lancet holder of lancing device with enough loading force, or (2) pulling the pulling cap of the lancing device with enough pulling force.

This study measured the loading force and pulling force of the candidate device, and the pressing force of priming button for the predicate device.

All results met acceptance criteria, which demonstrated that the lancets can be effectively and smoothly loaded into lancing device by end users.

8.2 Storage stability test

Storage stability test of candidate device was performed to ensure the safety and effectiveness were suitable for use over the shelf life of device.

8.3 Robustness test

Robustness test demonstrated that the TD-5010 Lancing Device was robust against cleaning

and disinfection procedures after multiple cleaning and disinfection cycles using EPA-registered disinfecting wipes.

Nonclinical tests were performed in accordance with 21 CFR 878.4850.
Clinical Testing is not applicable. Risks are analyzed to confirm that all identified risks were effectively mitigated. There were no special concerns of safety and effectiveness identified.

9. Conclusions

According to results of nonclinical tests, the **TD-5010 Lancing Device and TD-5084 Sterile Lancets** have a substantially equivalent safety and effectiveness profile to the predicate device (K214022).