September 11, 2020

MicroTech Medical, Inc.
℅ Mingzi Hussey
Principal Regulatory Consultant
Zi-Medical, Inc
253 Summer St
Somerville, MA 02143

Re: K193340
Trade/Device Name: GoChek Blood Glucose Monitoring System
GoChek Connect Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: August 11, 2020
Received: August 12, 2020

Dear Mingzi Hussey:

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 and Part 809); 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193340

Device Name
GoChek Blood Glucose Monitoring System

Indications for Use *(Describe)*

GoChek Blood Glucose Monitoring System

The GoChek Blood Glucose Monitoring System comprises of the GoChek Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193340

Device Name
GoChek Connect Blood Glucose Monitoring System

Indications for Use *(Describe)*

GoChek Connect Blood Glucose Monitoring System

The GoChek Connect Blood Glucose Monitoring System comprises of the GoChek Connect Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Connect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Connect Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Connect Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Connect Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Connect Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

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)

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GENERAL INFORMATION

1. **Type of Submission**

   Traditional 510(k) Submission
   510(k) number: k193340
   Submission date: 09/30/2019

2. **Submitter/Manufacturer information**

Submitter Name: MicroTech Medical, Inc.
Address: 1999 S. Bascom Ave, Suite 700, Campbell, CA 95008
Contact Person and Title: Dore Mark, Vice President
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Manufacturer Name: MicrotechMedical(Hangzhou) Co.,Ltd
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Contact Person and Title: Weiwei Zhu /RA Manager
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3. **Contact person**

   3.1 Primary Contact Person

Mingzi Hussey
Principal Regulatory Consultant at Zi-medical
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   3.2 Secondary Contact Person

Dore Mark
Vice President at MicroTech Medical,Inc.
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Contact Person and Title: Dore Mark, Vice President
Tel: +1408-5440744
Email: dore.mark@microtechmd.com

4. Proprietary Name of the device

GoChek Blood Glucose Monitoring System
GoChek Connect Blood Glucose Monitoring System

5. Common Name

Glucose Test System

6. Classification

Product code:NBW
Class: II
Regulation number: 862.1345
Glucose Test System

7. Predicate device

On Call Sharp Blood Glucose Monitoring System
ACON Laboratories, Inc.
510(k) number: k130284

8. Device information

006 510(k) Summary

Device name: GoChek Blood Glucose Monitoring System, GoChek Connect Blood Glucose Monitoring Systems

Proprietary Name	Model No.	Classification	Product Code	Description	Common Name
GoChek Blood Glucose Monitoring System	GoChek	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
GoChek Connect Blood Glucose Monitoring System	GoChek Connect	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter, Blue-Tooth	Glucose Test System

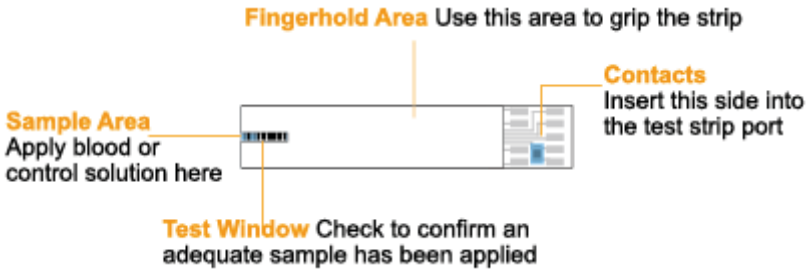
9. Description

GoChek Blood Glucose meter
Monitoring System

GoChek Connect Blood Glucose meter
Monitoring System

GoChek Blood Glucose Monitoring System and GoChek Connect Blood Glucose Monitoring System （also called “GoCheck series”） perform quantitative assays of glucose in fresh capillary whole blood obtained from the fingertip. The glucose measurement is achieved by using the amperometric detection method.

Both the systems share the same GoChek Blood Glucose test strips. It has a reagent system in test window that includes glucose dehydrogenase (FAD-GDH) and a mediator that reacts with the glucose in the whole blood sample. This reaction, in turn produces an electrical current that is measured by the meter’s electronics through test strip contact area. The meter, then calculates and displays the blood glucose concentration reading, calibrated to a plasma reference.



GoChek Connect Blood Glucose Monitoring System has Bluetooth and serial interfaces that comply with US federal guidelines, Part 15 of the FCC Rules for devices with RF capability.This Bluetooth function will allow user to transfer their test results from BG meter to a specific app which developed by MicroTech. Users can choose to utilize these function by following the instruction to set it up, otherwise these functions will remain shut off.

Pancares App

The Pancares App is available for both Android phones (through Google Play). The app uses the smartphone'sbluetooth radio to read data from the GoChek Connect meter's onboardmemory. Once the device wireless connection and app are connected, thedevice sends the glucose data and synchronizes the onboard history with theapp and allows the app to display this data for the user. The data that is

transferred to the smartphone is read only, and the smartphone has no way of altering the data residing on the GoChek Connect meter.

10. Intended Use/ Indications for Use

GoChek Blood Glucose Monitoring System

The GoChek Blood Glucose Monitoring System comprises of the GoChek Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

GoChek Connect Blood Glucose Monitoring System

The GoChek Connect Blood Glucose Monitoring System comprises of the GoChek Connect Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Connect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Connect Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Connect Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Connect Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Connect Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

11. Technological Characteristics

Specification of the GoChek Blood Glucose Monitoring System and GoChek Connect Blood Glucose Monitoring System:

Feature	**Specification**
Size	83.5mm (L) × 54mm (W) ×19mm (Thickness)
Glucose Test Range	10-580 mg/dL
Results Display	Plasma equivalent
Minimum Sample Volume	0.5uL
Test Time	5 seconds
Battery	CR 2032 3.0V coin cell battery
Battery life	>1,000 readings
Glucose Concentration Units	mg/dL
Memory Storage	500 test results with date and time
Auto Shutdown	Automatic shutdown after 2 minutes
Display Size	40mm× 42mm
Weight	about 50 grams (including battery)
Operating Temperature	41-113°F (5-45°C)
Operating Humidity	10-90% (non-condensing)
Hematocrit Range	10-70%
Sample	Fresh capillary whole blood

Sample Site	Fingertip
Data Port	Serial data port

12. Comparison to Predicate Devices

Predicate Device:

On Call Sharp Blood Glucose Monitoring System

510(k) Number: K130284

Features	GoChek/GoChek Connect Blood Glucose Monitoring System	On Call Sharp Blood Glucose Monitoring System (K130284)
Indications for Use	The GoChek Blood Glucose Monitoring System comprises of the GoChek Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Blood Glucose Monitoring System is intended for single-patient use and should not be shared. The GoChek Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Blood Glucose Monitoring System is not intended for the diagnosis of or screening for	The On Call Sharp Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Forearm and palm testing sites should be used alternately only when blood glucose level is not changing rapidly. The On Call Sharp Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

	diabetes.	
Detection Method	Amperometric electrochemical	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same
Calibration Coding	no-coding	Same
Test Range	10-580 mg/dL	20 – 600 mg/dL
Memory	500 records with time and date	Same
Sample Type	fresh capillary whole blood	Capillary whole blood
Sample Sites	Fingertip	Fingertip, forearm, palm
Sample Volume	0.5µL	0.6 µL
Sample Test Time	5 seconds	Same
Hematocrit Range	10 –70%	25 – 70%
Glucose Units of Measure	mg/dL	mg/dL
Operating Temperature	41-113°F (5-45°C)	50-113°F (10-45°C)
Operating Relative Humidity	10–90%	Same
Data Port	Serial data port	Same

Automatic Shutoff	Two minutes after last user action	Same
Power Source	Two CR 2032 3.0 V coin cell batteries	Two CR 2032 3.0V coin cell batteries
Meter Size	83.5 × 54 ×19mm	90 x 58 x 22 mm
Meter Weight	Approx. 50 grams (including battery)	Approx. 50 g (including batteries)
Battery Life	>1,000 readings	Minimum of 1,000 measurements (without considering data transfer and test reminder alarms)
Bluetooth (Only apply for GoChek Connect Blood Glucose Monitoring System)	BLE 4.0 version	None

13. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

13.1 Standard/Guidance Document Referenced

- FDA Guidance for Industry and Food and Drug Administration Staff - Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, October 2016
- Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic

Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology, April 2015

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 200521 CFR Part 803：The Medical Device Reporting (MDR) Regulation, April 2018.General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
- **CLSI/NCCLS EP06-A:** Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- **CLSI/NCCLS EP07-A2:** Interference Testing in Clinical Chemistry; Approved Guideline Second Edition
- **ISO 13485:2016:** Medical devices - Quality management systems – Requirements for regulatory purposes
- **EN 13532:2002**: General requirements for in vitro diagnostic medical devices for self-testing
- **EN 13612:2002/AC:2002:** Performance evaluation of in vitro diagnostic medical devices
- **EN 13640:2002/EN 13640:2002:** Stability testing of in vitro diagnostic reagents
- **EN 13641:2002**: Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- **EN ISO 14971:2012:** Medical devices - Application of Risk management to medical devices
- **EN ISO 15197:2015:** In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- **EN ISO 15223-1:2016:** Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)

- **EN ISO 17511:2003:** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- **EN ISO 18113-1:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 1: Terms, definitions and general requirements
- **EN ISO 18113-2:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 2: In vitro diagnostic reagents for professional use
- **EN ISO 18113-3:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 3: In vitro diagnostic instruments for professional use
- **EN ISO 18113-4:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 4: In vitro diagnostic reagents for self-testing
- **EN ISO 18113-5:2011:** In vitro diagnostic medical devices. Information supplied by the manufacturer (labeling). Part 5: In vitro diagnostic instruments for self-testing
- **EN 13640:2002:** Stability testing of in vitro diagnostic reagents
- **IEC 60068-2-64:2008:** Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
- **IEC/EN 61010-1:2010:** Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements
- **IEC 61010-2-101:2015:** Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- **EN 62366:2008:** Medical devices. Application of usability engineering to medical devices

- **IEC 60601-1-2:2014:** International Standard: Medical electrical equipment - Part 1-2:General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances - Requirements and tests
- **EN 62304:2006 / AC:2008: Medical device software. Software life-cycle processes**
- **ASTM D 4169-09A:** Standard Practice for Performance Testing of Shipping Containers and Systems
- **Council Directive 2002/95/EC:** on Waste Electrical and Electronic Equipment (WEEE Directive)
- **Council Directive 80/181/EEC of 20 December 1979:** EU Metric Directive
- **Council Directive 1999/103/EC:** amending council directive 80/181/ECC on the approximation of the laws of Member States relating to units of measurement
- **Directive 2011/65/EU:** on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- **EN 50581:2012:** Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- **IEC 62321:2008:** Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)

13.2 Performance Testing

The performance characteristics of the GoChek/ GoChek Connect Blood Glucose Monitoring System were evaluated by performing the following studies: within-run precision, intermediate precision, Linearity, Interference Evaluation(Endogenous/Exogenous Substances), Hematocrit Effect, Stability, System Operating Conditions Testing Study, Temperature Effect Study for Control Solution , Flex Study using sample Outside the Measuring Range, Sample Volume, Sample Perturbation Study, Intermittent Sampling, software validation testing,

electromagnetic compatibility, electrical safety testing, Random vibration test, Shock Testing and usability testing.

14. Discussion of Method Comparison/User Evaluation Performed

Method Comparison/User Evaluation were conducted with lay persons (including naïve and non-naïve SMBG users) using the GoChek series. .
The study data were presented evaluating the system accuracy of the GoChek series compared to the YSI Model 2300 STAT PLUS per the Microtech Method Comparison/User Evaluation Protocol for the GoChek/ GoChek Connect Blood Glucose Monitoring System.
In addition, studies using blood samples in the extreme upper and lower ends of the claimed measuring range (10 to 580 mg/dL) altered to achieve glucose concentrations of less than 80 mg/dL and greater than 250 mg/dLwas performed in a laboratory setting by trained professionals, wherein samples were measured and compared on both the GoChek series and YSI Model 2300 STAT PLUS.
Both above study results indicate that 95% of all SMBG results are within +/- 15% of the comparator results across the entire claimed measuring range of the device and that 99%of all SMBG results are within +/- 20% of the comparator results across the entire claimed measuring range of the device.
In addition, the participants in Method Comparison/User Evaluation were questioned and assessed the readability grade level of the user manual, test strip insert, and control solution insert prior to study.

15. Substantial Equivalence Conclusion

The laboratory testing and Method Comparison/User Evaluation study results demonstrate that the GoChek/GoChek Connect Blood Glucose Monitoring System is safe, effective and convenient. It also demonstrates that the GoChek/GoChek Connect Blood Glucose Monitoring System meets the accuracy requirements per Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use-Guidance for Industry and Food and Drug Administration Staff, October 11, 2016, and as such is

substantially equivalent to the On Call Sharp Blood Glucose Monitoring System. currently sold on the U.S. market(K130284).

The information provided in the 510(k) submission is sufficient to demonstrate the substantial equivalence of subject device to the predicate device.