January 27, 2023

Shanghai Genext Medical Technology Co., Ltd.
% Giselle Zhang
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K203833
Trade/Device Name: Tacrolimus Assay Kit
Regulation Number: 21 CFR 862.1678
Regulation Name: Tacrolimus Test System
Regulatory Class: Class II
Product Code: MLM
Dated: August 19, 2022
Received: August 19, 2022

Dear Giselle Zhang:

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,

Paula Caposino -S

Digitally signed by Paula Caposino -S
Date: 2023.01.27 15:31:02 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
k203833

Device Name
Tacrolimus Assay Kit

Indications for Use *(Describe)*
The Tacrolimus Assay Kit is used for quantitative determination of the tacrolimus concentration in human whole blood on the Beckman Coulter AU480. It is to be used as an aid in the management of liver and kidney allograft patients receiving tacrolimus therapy.

For In Vitro Diagnostic Use.

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.

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510(k) Summary

Submission Number: k203833

The following information is provided in accordance with 21 CFR 807.92:

Submitter Information

Company:	Shanghai Genext Medical Technology Co., Ltd.
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Regulatory Correspondent	Giselle Zhang
Email:	LST.AUS.ProjectManagement@ul.com
Date Summary Prepared:	January 24, 2023

Name of the Device

Device Trade Name:	Tacrolimus Assay Kit
Common Name:	Tacrolimus Assay Kit
Classification Name:	Toxicology
Review Panel	Clinical Chemistry (TX)
Regulation Number:	862.1678
Classification:	II
Product Code:	MLM

Intended Use:

Indications for Use:

The Tacrolimus Assay Kit is used for quantitative determination of the tacrolimus concentration in human whole blood on the Beckman Coulter AU480. It is to be used as an aid in the management of liver and kidney allograft patients receiving tacrolimus therapy.

For In Vitro Diagnostic Use.

Reagent:

- Reagent 1 (R1): FK506-protein complex, stored in MES buffer; Preservative: sodium azide.
- Reagent 2(R2): Latex particles sensitized by anti-FK506 monoclonal antibody, 4-(2-hydroxyerhyl) piperazine-1-erhaesulfonic acid; Preservative: sodium azide.

Pretreatment Reagent:

- Sample extractant: Containing methanol and inorganic salt protein denaturant.

Calibrator:

- Calibrator: Bovine whole blood solution containing different concentrations of FK506 (the calibration target list please see the following table); preservative.: sodium azide.

- The calibrators yield the following concentrations:

Calibrator name	Target value (ng/mL)
Calibrator A	0.0
Calibrator B	3.0
Calibrator C	6.0
Calibrator D	10.0
Calibrator E	20.0
Calibrator F	30.0

Special Conditions for use statement(s):

- For prescription use only.

Special Instrument Requirements:

- Beckman Coulter AU480.

Device Description

The Tacrolimus Assay Kit utilizes the latex-enhanced competitive immunoturbidimetry method for quantitative determination of the tacrolimus concentration in human whole blood. The assay consists of reagents, sample extract and calibrator.

Test Principle

The kit is based on the principle of latex-enhanced competitive immunoturbidimetry method; The sample should be pretreated, and the protein-bound tacrolimus in the whole blood should be extracted for detection before the tacrolimus concentration is determined in the detection process. FK506 in the sample competes with FK506 in the FK506- protein complex in the reagent to bind the anti-FK506 antibody on the surface of the sensitized latex particles. The higher the concentration of FK506 in the sample, the greater the degree to which the latex surface antibody is bound by it, and the lower the latex aggregation extent induced by FK506- protein complex. The turbidity of the reaction system is negatively correlated with the concentration of FK506 in the sample. Therefore, a calibration curve can be established and the concentration of the whole blood sample FK506 can be calculated by measuring the absorbance at 546 nm.

Substantial Equivalence Information

Predicate Device Identification:

ARCHITECT TACROLIMUS: MODEL lL 77 (K070820)

Comparison with Predicate:

Device & Predicate Device(s):	Candidate Device K203833	Predicate Device K070820
Device Trade Name	Tacrolimus Assay Kit	ARCHITECT Tacrolimus Assay
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	For the quantitative determination of tacrolimus in human whole blood.
Sample pre-treatment	Same	Manual

General Device Characteristic Differences	Candidate Device K203833	Candidate Device K070820
Measuring Range	1.5 – 30 ng/mL	2 – 30 ng/mL
Methodology	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)	Chemiluminescent microparticle immunoassay
Analyzer platform	Beckman Coulter AU480 analyzer	ARCHITECT i System.

Summary of Testing:

Analytical studies were performed to evaluate the precision, linearity, assay reportable range, recovery, specificity, and accuracy of the candidate device.

Conclusion:

Tacrolimus Assay Kit has the same indications for use as the predicate device. Any minor differences in the technological characteristics of the subject device when compared to the predicate device have been evaluated through performance testing which demonstrates that the Tacrolimus Assay Kit is substantially equivalent.