August 11, 2021

CD Diagnostics Inc
Pragnya Bakka
Regulatory Affairs Specialist
650 Naamans Road Suite 100
Claymont, Delaware 19703

Re: K212204
Trade/Device Name: Synovasure Alpha Defensin Lateral Flow Test Kit (1 Kit), Synovasure Alpha Defensin Lateral Flow Test Kit (5 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (10 Test), Synovasure Alpha Defensin Flow Test Kit (30 Test), Synovasure Alpha Defensin Control Kit
Regulation Number: 21 CFR 866.3230
Regulation Name: Device To Detect And Measure Non-Microbial Analytes To Aid In The Detection And Identification Of Localized Human Infections
Regulatory Class: Class II
Product Code: QGN
Dated: July 14, 2021
Received: July 15, 2021

Dear Pragnya Bakka:

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,

Maria Ines Garcia, Ph.D.
Branch Chief
Division of Microbiology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
DEN180032

Device Name
Synovasure Alpha Defensin Lateral Flow Test Kit

Indications for Use *(Describe)*
The Synovasure Alpha Defensin Lateral Flow Test Kit is a qualitative visually read immunochromatographic assay for the detection of human host response proteins, Alpha Defensins 1-3, in the synovial fluid of adults with a total joint replacement who are being evaluated for revision surgery. The Synovasure Alpha Defensin Lateral Flow Test Kit results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of periprosthetic joint infection (PJI). The Synovasure Alpha Defensin Lateral Flow Test Kit is not intended to identify the etiology or severity of a PJI.

The Synovasure Alpha Defensin Control Kit is used in the Synovasure Alpha Defensin Lateral Flow Test Kit as assayed quality control samples to monitor performance and reliability of the Synovasure Alpha Defensin Lateral Flow Test Kit.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Synovasure Alpha Defensin Lateral Flow Test Kit 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:	CD Diagnostics Inc. 650 Naamans Road, Suite 100, Claymont, DE, 19703.(302-367-7770)
Contact Person:	Pragnya Bakka Regulatory Affairs Specialist Telephone: (973-307-8038) Fax: (302-367-7771)
Date:	14-July-2021
Subject Device:	**Trade Name:** Synovasure Alpha Defensin Lateral Flow Test Kit, Synovasure Alpha Defensin Lateral Flow Test Kit (5 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (10 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (30 Test), Synovasure Alpha Defensin Control Kit **Classification Name:** • QGN– Lateral Flow Immunochromatography Assay For Host Infection Biomarkers (21 CFR 866.3230)

Predicate Device(s):	DEN180032	Synovasure Alpha Defensin Lateral Flow Test Kit, Synovasure Alpha Defensin Lateral Flow Test Kit (5 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (10 Test), Synovasure Alpha Defensin Lateral Flow Test Kit (30 Test), Synovasure Alpha Defensin Control Kit	CD Diagnostics Inc.

Device Description:

The Synovasure Alpha Defensin (AD) Lateral Flow (LF) Test Kit is an immunoassay for the detection of alpha defensin levels in the synovial fluid of patients with a potential PJI. Antibodies specific to alpha defensin bind host alpha defensin in the synovial fluid, become immobilized on the lateral flow test strip, and are detected as a colored line due to the use of a colloidal gold reporter.

Intended Use and Indications for Use:

The Synovasure Alpha Defensin Lateral Flow Test Kit is a qualitative visually read immunochromatographic assay for the detection of human host response proteins, Alpha Defensins 1-3, in the synovial fluid of adults with a total joint replacement who are being evaluated for revision surgery. The Synovasure Alpha Defensin Lateral Flow Test Kit results are intended to be used in conjunction with other clinical and diagnostic findings as an aid in the diagnosis of periprosthetic joint infection (PJI). The Synovasure Alpha Defensin Lateral Flow Test Kit is not intended to identify the etiology or severity of a PJI.

The Synovasure Alpha Defensin Control Kit is used in the Synovasure Alpha Defensin Lateral Flow Test Kit as assayed quality control samples to monitor performance and reliability of the Synovasure Alpha Defensin Lateral Flow Test Kit.

Summary of Technological Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • Intended Use: Same as the predicate device • Indications for Use: Same as the predicate device • Materials: Same as the predicate device • Design Features: Similar to predicate device with minor modifications • Sterilization: Not applicable
Summary of Performance Data (Nonclinical and/or Clinical)	• **Non-Clinical Tests:** o Method comparison study to demonstrate equivalent performance between proposed device with modified cassette geometry and existing version of the Alpha Defensin Lateral Flow Test Device was performed. • **Clinical Tests:** o NA
Substantial Equivalence Conclusion	The information provided within this submission demonstrates that the Synovasure Aplha Defensin Lateral Flow Test Kit is substantially equivalent to the predicate device