



November 24, 2020

Acarix A/S
Mette Munch
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Denmark

Re: DEN190047
Trade/Device Name: CADScor System
Regulation Number: 21 CFR 870.1420
Regulation Name: Coronary artery disease risk indicator from acoustic heart signals
Regulatory Class: Class II
Product Code: QMW
Dated: October 29, 2019
Received: November 4, 2019

Dear Mette Munch:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the CADScor System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The intended use of the CADScor System is to record heart sounds, murmurs and vibration for calculation of a patient specific score, indicating the risk of presence of coronary stenosis, as an aid in cardiac analysis and diagnosis.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the CADScor System, and substantially equivalent devices of this generic type, into Class II under the generic name Coronary Artery Disease risk score from acoustic heart waveforms.

FDA identifies this generic type of device as:

Coronary artery disease risk indicator using acoustic heart signals. A coronary artery disease risk indicator using acoustic heart signals is a device that records heart sounds including murmurs and vibrations to calculate a patient-specific risk of presence of coronary artery disease, as an aid in cardiac analysis and diagnosis.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 4, 2019, FDA received your De Novo requesting classification of the CADScor System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CADScor System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the CADScor System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

| Identified Risks to Health | Mitigation Measures |
|--|---|
| Adverse tissue reaction | Biocompatibility evaluation; Labeling; and Usability testing |
| Skin burn/irritation | Electrical safety testing; and Electromagnetic compatibility testing |
| False positive leading to unnecessary medical procedures | Software verification, validation, and hazard analysis; Usability testing; Acoustic performance testing; Clinical performance testing; and Labeling |
| False negative leading to failure to detect coronary artery disease | Software verification, validation, and hazard analysis; Usability testing; Acoustic performance testing; Clinical performance testing; and Labeling |
| Delay in calculation due to device failure resulting in a delay of treatment | Software verification, validation, and hazard analysis; Clinical performance testing; Usability testing; Acoustic performance testing; and Labeling |

In combination with the general controls of the FD&C Act, the coronary artery disease risk indicator using acoustic heart signals is subject to the following special controls:

- (1) Clinical performance testing must fulfill the following:
 - a. Testing must include a discussion of the patient population and any statistical techniques used for analyzing the data; and
 - b. Testing must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.
- (2) Acoustic performance testing must evaluate microphone sensitivity, sound acquisition bandwidth, and amplitude accuracy. The acoustic sensor specifications and mechanism used to capture heart sounds must be described.
- (3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must fulfill the following:
 - a. All inputs and outputs of the algorithm must be fully described;
 - b. The procedure for segmenting, characterizing and classifying the acoustic signal must be fully described; and
 - c. This justification must include verification of the algorithm calculations and validation using an independent data set.
- (4) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (5) Software verification, validation, and hazard analysis must be performed.
- (6) Human factors/usability testing must demonstrate that the user can correctly use the device, including device placement, based solely on reading the directions for use.
- (7) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.
- (8) Labeling must include the following:
 - a. A description of what the device measures and outputs to the user;
 - b. Instructions for proper placement of the device;
 - c. Instructions on care and cleaning of the device;
 - d. Warnings identifying sensor acquisition factors that may impact measurement results and instructions for mitigating these factors; and
 - e. The expected performance of the device for all intended use populations and environments.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the coronary artery disease risk indicator using acoustic heart signals they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Kimberly Crowley at 301-796-6017.

Sincerely,

for

Bram Zuckerman, M.D.

Director

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health