



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2016

Nihon Kohden Corporation
% Thomas Bento
Senior Vice President of QA/RA
Nihon Kohden America, Inc.
15353 Barranca Parkway
Irvine, California 92618

Re: K152305

Trade/Device Name: Nihon Kohden Afib Detection Program QP-039P

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)

Regulatory Class: Class II

Product Code: DSI

Dated: March 9, 2016

Received: March 11, 2016

Dear Thomas Bento:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

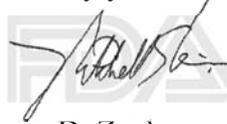
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152305

Device Name

Nihon Kohden Afib Detection Program QP-039P

Indications for Use (Describe)

The intended use of Afib detection program (QP-039P software) is used for processing adult patient ECG and detecting if atrial fibrillation (AF) is present continuously for more than 2.5 minutes. QP-039P software is intended to be used by qualified health care professionals in hospital or clinical environment.

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
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Nihon Kohden Afib Detection Program QP-039P 510(k) Summary

K152305

510(k) Summary for Nihon Kohden QP-039P Afib Detection Program

Submitter: Nihon Kohden Corporation
Address: 1-31-4 Nishiochiai, Shinjuku-ku
Tokyo, JAPAN 161-8560
Phone number: (949) 268-7708
Fax number: (949) 580-1550

Contact person: Tom Bento
Phone number: (949) 268-7708
Fax number: (949) 580-1550

Date prepared: August 05, 2015

Device name: Afib Detection Program QP-039P
Common name: Arrhythmia detector
Product Code: DSI
Regulation: 21 CFR 870.1025

Substantial equivalence claimed to: K964122 HP STAR ST and Arrhythmia Software which is the sponsor and primary predicate device and K080461 Philips Star ST and Arrhythmia Software as the reference predicate device which includes the Atrial Fibrillation detection that our device is claiming substantial equivalence to.

Description:

The following section provides an overview of QP-039P features that are controlled by software, and the intended operational environment.

QP-039P is the atrial fibrillation (AF) processing software. The software is intended to detect AF using patient's ECG. The Software is "Modular" and is to be used as an accessory to Patient Monitoring Devices (Host Devices). The software has a specific function to detect AF using RR interval and P wave and provides the result of atrial fibrillation detection to other software modules (See Figure1-1).

AF detection is performed using both the RR intervals and the P waves of input ECG. More precisely, the algorithm uses three features of input ECG to output AF detection result; RR irregularity, PR interval variability, and P wave variability.

The software detects if atrial fibrillation (AF) is present or not by 2 minutes of analysis at the earliest, and notifies AF presence every time it is detected.

Functionality shall include:

1. QP-039P receives RR intervals and ECG wave from other software modules.
2. QP-039P detects AF using three features for AF detection which are derived from input data, including RR irregularity, PR interval variability, and P wave variability.
3. QP-039P provides that AF is present or not to other software modules.

Nihon Kohden Afib Detection Program QP-039P 510(k) Summary

K152305

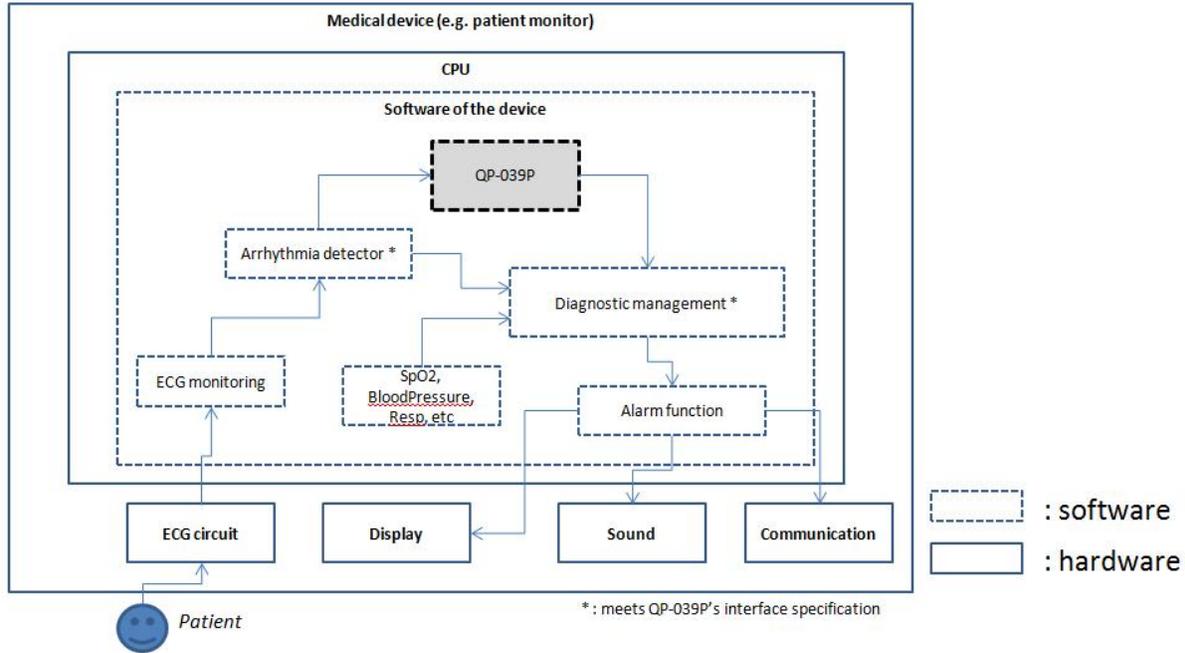


Figure 1-1 Relations of QP-039P and other software modules and hardware devices in the host device

Indications for Use:

The intended use of Afib detection program (QP-039P software) is used for processing adult patient ECG and detecting if atrial fibrillation (AF) is present continuously for more than 2.5 minutes. QP-039P software is intended to be used by qualified health care professionals in hospital or clinical environment.

Technological Characteristics - Substantial Equivalence Discussion

The Afib Detection Program QP-039P is substantially equivalent to the predicate device, Philips STAR (K080461). Differences between the devices are minor and do not raise questions regarding safety or efficacy. Minor differences in the performance between the two devices are explained below.

1. Indications for Use: The QP-039P does not have all the features of the predicate device and only references the features relating to detecting atrial fibrillation.

Test Summary

Performance testing for the QP-039P includes software verification tests, system validation testing, and testing to compliance standards. Traceability has been documented between all system specifications to validation test protocols.

Standards testing includes:

1. AAMI/ANSI EC 57:2012 Testing and Reporting Performance Results of Cardiac Rhythm and ST-segment Measurement Algorithms

Nihon Kohden Afib Detection Program QP-039P 510(k) Summary

K152305

2. IEC 62304 First Edition 2006-05, Medical Device Software – Software Life Cycle Processes

Verification and validation testing includes:

1. Code inspections
2. Unit level testing
3. Integration level testing
4. System level testing
5. ECG waveform database testing

Nihon Kohden Afib Detection Program QP-039P 510(k) Summary

K152305

1.1. Test Summaries for Selective Tests

The following table provides a summary of the key tests performed to demonstrate proper functional operation, correct implementation of risk control measures, and support substantial equivalence of the Afib detection program QP-039P.

Protocol	Summary	Results	Protocol/ Report No.
Code inspections	The review that checking whether the program was implemented as it was designed.	Pass	See V&V Report A701-033701 A701-033753 A701-033977
Unit level testing	Unit level testing tests that all software units perform those intended function. It is checked that software unit outputs intended value depending on input value. And it is checked that software unit performs according to design with executing step by step.	Pass	See V&V Report
Integration level testing	Integration level testing tests that transfer of data and control among software units and software items. It is checked that integrated software outputs intended value depending on input value.	Pass	See V&V Report A276-006524
System level testing	Comprehensive testing of the functional requirements in the required hardware platforms described in SRS , version 01-01	Pass	See V&V Report A277-004317
ECG waveform database testing	Comprehensive testing of the performance requirements described in SRS , version 01-01	Pass	See V&V Report A152-009761

Conclusion:

The performance of the Afib Detection Program QP-039P is substantially equivalent to the sponsor and primary predicate device, **HP STAR ST and Arrhythmia Software (K964122) and the reference predicate device the Philips Star ST and Arrhythmia Software (K080461)**. The QP-039P raises no safety or effectiveness issues and performs as well or better than the predicate devices.