K101521 P1/2

Philips Medical Systems

PHILIPS

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

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JUL 29 2010

This summary was prepared on May 28, 2010.

2. The name of this device is the Philips ST/AR ST and Arrhythmia Software, Release K.0. Classification names are as follows:

Classification	ProCode	Description
870.1025, II	74 MLD	Monitor, ST Alarm
870.1025, II	74 DSI	Arrhythmia Detector and Alarm
None	74 MHX	Physiological Monitor, Patient Monitor

3. The new device is substantially equivalent to the previously cleared ST/AR ST and Arrhythmia Software device marketed pursuant to K080461, K964122, K991773, K001348, K003621, K014261, K021251, K033513, K040357, K070260 and the Philips ECG Algorithm K073376, the Philips EASI ECG K033515, the GE 12RL Algorithm K060307, and the Siemens Infinity MultiView Workstation K030738.

4. The modification is a software-based change that adds the following features:
   - Support derived 12-lead ECG (RLS ECG) from a 6-electrode lead set.
   - Provide enhanced AF and Irregular HR alarms detection
   - Provide enhanced QT and ST analysis and alarms.

5. The new device has the same Indications for Use and Intended Use as the legally marketed predicate devices.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and

test results showed substantial equivalence. The results demonstrate that ST/AR Release K.0 meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Philips Medical Systems
c/o Ms. Lois Giegerich
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JUL 2 9 2010

Re: K101521
Device Name: Philips ST/AR ST and Arrhythmia Software, Release K.0
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection or Alarms)
Regulatory Class: Class II (Two)
Product Codes: MHX, MLD, DSI
Dated: June 30, 2010
Received: July 8, 2010

Dear Ms. Giegerich:

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.

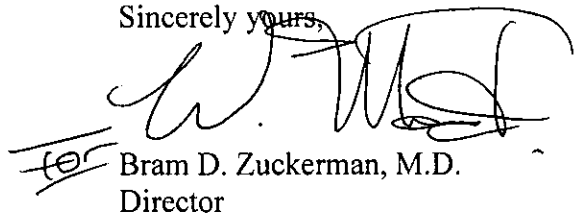
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

P1/1

K101521

1.1 ODE Indications Statement

JUL 2 9 2010

Indications for Use

510(k) Number (if known): K101521

Device Name: ST/AR ST and Arrhythmia Software

Indications for Use:

Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

The intended use of the ST/AR cardiotach is to monitor a neonatal, pediatric, or adult patient's ECG for heart rate and produce events/alarms for one or two ECG leads. The cardiotach function is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR arrhythmia analysis algorithm is to monitor a neonatal, pediatric, or adult patient ECG's for heart rate and ventricular arrhythmias, and produce events/alarms for one or two ECG leads. The arrhythmia analysis algorithm is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR ST analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST analysis algorithm is capable of monitoring paced and non-paced adult patients.

Note: The ST algorithm does not analyze ventricularly paced or ventricular ectopic beats.

The intended use of the ST/AR QT/QTc analysis is for use by the physician in the risk assessment process indicated for neonatal, pediatric and adult patients with and without symptoms of arrhythmia. QT measurement is intended to be used by qualified health professionals in hospital or clinical environments. Composite QT (single or multi-lead derived) measures the interval only and is not intended to produce any interpretation or diagnosis of those measurements.

EASI ECG is intended for monitoring multiple leads of ECG of adults, pediatrics and neonates.
EASI ECG is indicated for use by health care professionals whenever there is a need to monitor ECG of adult, pediatric, or neonatal patients including arrhythmia monitoring or ST segment changes of adult patients, to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

RLS ECG is intended for monitoring multiple leads of ECG of adults.
RLS ECG is indicated for use by health care professionals whenever there is a need to monitor ECG of adult patients including arrhythmia, ST segment changes, and QT/QTc, to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

Prescription Use YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101521