

K133622 page 1 of 4

**Premarket Notification 510(k) Summary  
As required by section 807.92**

**MAC™ 2000 ECG Analysis System**

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

Date: [4<sup>th</sup> Nov 2013]  
Submitter: Wipro GE Healthcare Private Ltd.  
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 GE Healthcare  
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Device:        Trade Name:    **MAC™ 2000 ECG Analysis System**

Common/Usual Name:            Electrocardiograph  
Classification Names:            Electrocardiograph,  
    Programmable Diagnostic Computer,  
    Transmitter receiver Electrocardiograph, Telephone

Product Code:                    DPS,  
    DQK,  
    DXH

Regulation No:                    21 CFR 870.2340,  
    21 CFR 870.1425,  
    21 CFR 870.2920

Predicate Device(s):                MAC 1600 ECG Analysis System  
    MAC 5500 ECG Analysis System  
    MAC 800 ECG Analysis System

Regulatory Class                    II

Prescription Status                Prescription Device

Device Classification Panel        Cardiovascular

Device Description:                The MAC™ 2000 ECG analysis system can print and display multiple leads of ECG data. The device is capable of acquiring 2 additional ECG leads beyond what is needed for classical 12 lead ECG acquisition.

The MAC™ 2000 ECG analysis system provides ECG measurement in both resting and stress mode. The device also supports arrhythmia as a mode of operation.

The Hook up advisor feature in MAC™ 2000 ECG analysis system advises the users of poor lead quality based on noise measurement.

The MAC™ 2000 ECG Analysis System delivers multiple leads of ECG on full-size reports and includes an alphanumeric keyboard for patient demographics and other data entry, an integrated 7" color display, and an integrated thermal writer. The thermal writer will print real time continuous waveform, alphanumeric data and non real time reports.

The device has an optional feature of transmission and reception of ECG data, downloading of orders and patient demographics to and from a central ECG cardiovascular information system and supports exporting of ECG records in PDF. It also has an optional internal memory and removable storage to store resting ECG records.

The patient information can be entered with the help of optional bar code reader.

Clinical Trials Data Guard and audit trail options are also available to support electronic record requirements.

MAC™ 2000 ECG Analysis system can be used as a portable unit also.

Indication for Use: The MAC™ 2000 ECG analysis system is a portable device intended to be used by or under the direct supervision of a licensed healthcare practitioner using surface electrodes to acquire, analyze, display, and record information for adult and pediatric populations in a hospital, medical professional's facility, clinics, physician's office or outreach centers.

NOTE: Pediatric populations are defined as patients between the ages of 0 and 15 years.

The MAC™ 2000 ECG analysis system provides the following modes of operation:

- Resting ECG mode
- Arrhythmia mode
- Exercise mode for exercise stress testing (optional)
- RR analysis mode for RR interval analysis (optional)

The basic system prints 6 or 12 leads of ECG and is upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis. Arrhythmia detection is provided for the convenience of automatic documentation.

Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

Technology: MAC™ 2000 ECG Analysis System uses the same fundamental technology as its predicate device MAC1600 ECG Analysis System in acquiring, analyzing, recording, displaying and printing ECG data for both adult and pediatric populations.

The basic system prints 6 or 12 leads of ECG and provides optional transmission and reception of ECG data to and from a central ECG cardiovascular information system. The system can be upgraded with software options such as stress testing, interpretive analysis, storage and communication options which is similar to predicate device.

The intended use of the predicate device differs from the proposed device on verbiage as it has been modified to increase clarity and also on the offering of RR analysis mode of operation which is not available for sale in United States.

MAC™ 2000 ECG Analysis System is similar to MAC 5500 Resting ECG Analysis Systems K073625 in the technology of downloading orders and patient demographics from a central ECG cardiovascular information system.

MAC™ 2000 ECG Analysis System makes use of the similar technology of exporting ECG reports in PDF and WiFi communication from MAC800 Resting ECG Analysis System K090212.

For more on the predicate device comparison refer to section 12 of this 510K submission.

Performance Standards The MAC™ 2000 ECG Analysis System complies with the voluntary standards as detailed in Section 9 of this submission.

Sterilization Not Applicable

Determination of Substantial  
Equivalence:

Summary of Non-Clinical Tests:

Verification and Testing activities establish the performance, functionality, usability, safety, and reliability characteristics of MAC™ 2000 ECG analysis system.

MAC™ 2000 ECG analysis system comply with voluntary standards as detailed in Section 09, 15, 16, 17 and 18 of this premarket submission.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews

Summary of Simulated Use Setting:

The Design verification of MAC™ 2000 ECG analysis system has been divided into several protocols that include electrical, mechanical, safety testing, reliability, and system design verification.

The performance testing included testing on unit level, system level, as well as usability and safety parameters.

The results of the Design verification testing protocols have been documented in Section 18 of this 510(k) application.

The results demonstrate that MAC™ 2000 ECG analysis system meets all design requirements and performance claims.

The subject of this premarket submission, MAC™ 2000 ECG analysis system, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MAC™ 2000 ECG analysis system to be as safe and as effective as the predicate device, and the performance to be substantially equivalent to the predicate device.



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

January 23, 2014

Wipro GE Healthcare  
Douglas Kentz  
8200 West Tower Ave  
Milwaukee, WI 53223 US

Re: K133622  
Trade/Device Name: MAC 2000 ECG Analysis System  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Electrocardiograph  
Regulatory Class: Class II  
Product Code: DPS, DQK, DXH  
Dated: November 20, 2013  
Received: November 22, 2013

Dear Douglas Kentz:

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 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>. 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 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,

**Owen P. Faris -S**

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

Enclosure

K133622

**Indications for Use**

510(k) Number (if known):

Device Name: MAC™ 2000 ECG analysis system

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Arrhythmia detection is provided for the convenience of automatic documentation. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use     
(Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by  
Owen P. Faris -S  
Date: 2014.01.23  
15:35:48 -05'00'