

K972498

## 510(k) Summary

FEB 17 1998

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**Date** November 18, 1997

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**Contact** Darlene T. Korab  
Sr. Project Manager  
Regulatory Affairs  
Johnson & Johnson Medical, Inc.  
4110 George Road  
Tampa, FL 33634  
Telephone: (813) 887-2663  
Telefax: (813) 887-2263  
E Mail: dkorab@crtus.jnj.com

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**Device Name** • OBSERVER\* Central Station

The subject of this premarket notification is the modification of the currently marketed Johnson & Johnson Medical, Inc. OBSERVER Central Station (K933404) to include ST-segment measurement.

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**Common Name** • Central Station

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**Classification** The classification name, 21 Code of Federal Regulations (CFR) Part and Paragraph number and classification of the OBSERVER Central Station with ST-segment measurement follow. The tier categorization based on the list (January 27, 1994) distributed by the Office of Device Evaluation is also included.

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## 510(k) Summary, Continued

Classification,  
continued

Classification name, 21 CFR section, class and tier are as follows:

Classification Name	21 CFR Section	Class	Tier
Monitor, Electrocardio- graphic	870.2360	II	2
Transmitters and receivers, physiological signal, radiofrequency	870.2910	II	2
Detector and alarm, Arrhythmia	870.1025	III	3

Predicate  
Devices

The addition of ST-segment measurement to the currently marketed OBSERVER Central Station with arrhythmia analysis is substantially equivalent to the currently marketed OBSERVER Central Station with arrhythmia analysis which received market clearance February 9, 1994 via 510(k) K933404. Everything remains the same except for the addition of ST-segment measurement. The added ST-segment measurement feature is substantially equivalent to the ST-segment measurement feature of the currently marketed VitalCom, Inc. VCOM Central Monitor which received market clearance on January 30, 1995 via VitalCom 510(k) K942147. The same firm – VitalCom, Inc. -- that is developing the ST-segment software for the OBSERVER Central Station developed the ST-segment software for the VitalCom, Inc. VCOM Central Monitor.

Predicate Devices	510(k) Number
OBSERVER Central Station	K933404
VCOM Central Monitor	K942147

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## 510(k) Summary, Continued

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**Device  
Description**

ST-segment measurement is an optional feature of the OBSERVER Central Station with arrhythmia analysis. This feature allows for the measurement of the ST-segment level and slope and the issuance of alarms for ST elevations and depressions. The clinician may adjust certain waveform points and alarm priority and limits or rely on default settings for each patient to be analyzed.

The OBSERVER Central Station (K933404) is a PC-based monitoring system designed to provide remote surveillance with alarms, trending and retrieval of wave-form and numeric physiological data for up to 8 patients who are monitored via various DINAMAP\* Physiological Monitors or other appropriate bedside/patient monitors.

The OBSERVER Central Station displays, records and stores physiological data including ECG, non-invasive and invasive blood pressure, heart rate, temperature and pulse oximetry. The system is designed to be used with a hardwire interface using RS 232; wireless connectivity using 900 MHz spread spectrum or fixed frequency; or VHF (174-216 MHz, TV channels 7 through 13), including patient-worn telemetry. Monitors that may be networked with the OBSERVER Central Station for ECG include members of the Johnson & Johnson Medical Inc. DINAMAP\* family of monitors, such as the DINAMAP MPS\* *Select*\* Monitor (K955113) and the DINAMAP\* PLUS Monitor (K943709 and K912188), and patient-worn ECG VHF telemetry (VitalCom, Inc. K942147). The OBSERVER Central Station uses a Pentium PC with an SVGA, touch or non-touch, color monitor. Recordings can be made on either the built-in two-channel thermal recorder or with an optional HP LaserJet\* Printer. Also optional is full disclosure (history) of all waveforms.

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## 510(k) Summary, Continued

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### **Indications**

The OBSERVER Central Station with ST-segment measurement is a prescription device intended for use only by health care professionals. The device is used for the remote monitoring of physiological parameters, including non-invasive and invasive blood pressure; invasive hemodynamic and intracranial pressures; oxygen saturation via pulse oximetry; temperature; ECG ; and pulse/heart rate of adult, pediatric and neonatal patients. The device is located at a distance from the patient but within the same facility, including settings such as hospital and outpatient services, including general medical/surgical, critical care, intermediate/step-down care, emergency room, radiology, labor and delivery, operating and recovery room, cardiac catheterization lab, endoscopy and same-day surgery.

Arrhythmia detection and ST-segment measurement are optional ECG features limited to the adult population. ST-segment measurement is contraindicated in paced patients. The ST-segment feature of the OBSERVER Central Station provides for the measurement of the ST-segment level and slope of the ECG waveform, alerting the clinician to ST-segment changes. The significance of ST-segment changes must be determined by a clinician. The device is not designed, sold or intended for use except as indicated.

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### **Technological Characteristics**

The OBSERVER Central Station with ST-segment measurement has the same technological characteristics as the predicate devices. The modification of the device software is an enhancement of the arrhythmia analysis feature to allow for the measurement of the ST segment with corresponding alarms. The methodology for ST-measurement is virtually the same as the VitalCom, Inc. VCOM Central Monitor.

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## 510(k) Summary, Continued

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**Performance** The ST-enabled arrhythmia analysis software was tested against the AHA and MIT databases to measure the algorithm's QRS detection sensitivity and positive predictivity and ventricular beat identification sensitivity, positive predictivity and false positive rate.

The algorithm was also tested against the European ST-T database to measure the algorithm's ST sensitivity, positive predictivity and peak error.

Software validation was performed to show that the OBSERVER Central Station correctly processes ST information, while not affecting other portions of the system.

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**Conclusions** In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Johnson & Johnson Medical concludes that the modified device, the OBSERVER\* Central Station with ST-segment measurement is safe, effective and substantially equivalent to the predicate devices as described herein.

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**Other Information** Johnson & Johnson Medical, Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Darlene T. Korab  
Johnson & Johnson Medical Inc.  
4110 George Road  
Tampa, FL 33634

FEB 17 1998

Re: K972498  
OBSERVER\* Central Station  
Regulatory Class: III (Three)  
Product Code: 74 DSI  
Dated: November 18, 1997  
Received: November 19, 1997

Dear Ms. Korab:

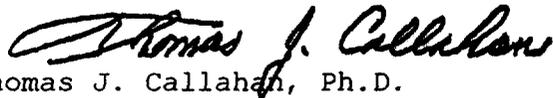
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

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510(k) Number (if known): K972498

Device Name: OBSERVER\* Central Station

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
(per 21 CFR 801.109)

OR

Over-The Counter Use

(Optional Format 1-2-96)

\*Trademark