



MAR 13 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lorraine R. Fredes  
Witt Biomedical Corporation  
295 North Drive, Suite H  
Melbourne, FL 32934

Re: K973474  
Central Station with Advanced Patient Care Monitoring Systems  
Regulatory Class: II (two)  
Product Code: 74 MHX  
Dated: February 24, 1998  
Received: February 26, 1998

Dear Ms. Fredes:

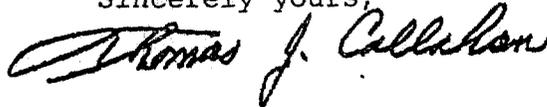
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): k973474

Device Name: Witt Biomedical Corporation Central Station with Advanced Patient Care Monitoring System.

Indications For Use:

The Witt Biomedical Central Station Monitor and Advanced Patient Care Monitoring Units are designed to monitor, store and display patient data. User adjustable alarms (both visual and audible), alert the operator to anomalous occurrences and facilitate timely responses. The Witt Biomedical Central Station Monitor and/or Advanced Patient Care Monitoring unit are intended for use in hospital environments including coronary care, post anesthesia recovery, operating room, critical care, surgical intensive care, respiratory intensive care, medical intensive care, pediatric intensive care, neonatal intensive care and patient holding areas of health care facilities. The Witt Biomedical Central Station Monitor and Advanced Patient Care Monitoring Unit offers a thorough list of monitoring parameters which use proven algorithms of the Witt Biomedical Series IV. Patient information is displayed in a logical, easily understood format that requires minimal training. Operation parallels the Witt Series IV, affording familiarity to the users of any Witt Biomedical system.

The Witt Biomedical Central Station Monitor and Advanced Patient Care Monitoring Units are intended for use by physicians, physician assistants, registered nurses, or other qualified hospital personnel with training on the operation of this equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Mr. Pugh*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number k973474

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)