Home Monitoring System with the BA03 DDDR Pulse Generator - P950037s019

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Home Monitoring System with the BA03 DDDR Pulse Generator
Manufacturer:	BIOTRONIK Inc.
Address:	6024 Jean Road, Lake Oswego, OR 97035
Approval Date:	October 11, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p950037s019a.pdf

What is it? The BIOTRONIK Home Monitoring System lets doctors check patients who have the Biotronik pacemaker between office visits. The system records data about the patient's heart and pacemaker and sends the information to BIOTRONIK's Service Center via a cell phone. The Service Center analyzes the data and forwards it to the patient's doctor. All data is confidential. This monitoring can be performed any time, and it can take place anywhere the patient goes within the area served by the cell phone provider.

How does it work? This new type of pacemaker contains a tiny transmitter (sender) that sends signals by radio waves (RF) to a small portable cell phone that is carried by the patient in a pocket or handbag. The RF receiver sends the patient data to the BIOTRONIK Service Center for analysis. The information is then sent to the doctor by FAX.

When is it used? The BIOTRONIK Home Monitoring system is available to any patient who receives the BIOTRONIK pacemaker. The device is designed to provide the doctor with additional information between regularly scheduled office visits. It is designed to send patient and pacemaker data once each day to the Service Center, but it can also be programmed to send data when the patient has symptoms such as faintness, dizziness, or irregular heartbeat.

What will it accomplish? The Home Monitoring System allows the doctor to more closely monitor the patient's condition and to change the medical treatment if necessary. Home Monitoring allows the doctor to check the function of the pacemaker without seeing or speaking with the patient.

When should it not be used? The BIOTRONIK Home Monitoring system cannot be used if the patient lives in an area where cell phone coverage is not available.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p950037s019.html

Other:

FDA Talk Paper: http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01108.html
National Institutes of Health (NIH) MedlinePlus on pacemakers:
http://medlineplus.nlm.nih.gov/medlineplus/ency/article/007070.htm
NIH MedlinePlus article on Biotronik:
http://www.nlm.nih.gov/medlineplus/news/fullstory_4159.html

(Updated 10/31/2001)