



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 10 2002

Mr. Robert Duffy  
Director of Product Development  
Pulse Metric, Inc.  
11777 Sorrento Valley Road  
San Diego, CA 92121

Re: K013478

Trade Name: DynaPulse 5200A Pathway Blood Pressure Monitor System

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive blood pressure measurement system.

Regulatory Class: II (two)

Product Code: DXN

Dated: December 23, 2001

Received: January 2, 2002

Dear Mr. Duffy:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

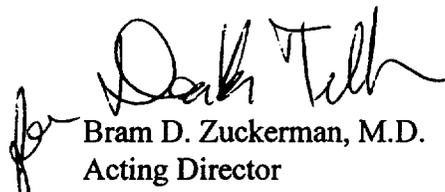
Page 2 - Mr. Robert Duffy

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

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

Enclosure

## Indications for Use Statement

**U.S. Food and Drug Administration, Center for Devices and Radiological Health**

510(k) Number: K013478

Device Name: DynaPulse 5200A Pathway Non-Invasive Blood Pressure Monitor

### Indications for Use:

The DynaPulse 5200A Pathway is indicated for trained medical professionals to operate on patients at clinical settings to collect and measure blood pressure and pulse rate information. In addition, the DynaPulse DP5200A Pathway is indicated for patients at home who are capable and willing to self-administrate this device upon prescription of their healthcare provider. The DP5200A monitor must be connected to an IBM PC-compatible computer that is concurrently running DP5200A Pathway PC Software. The device does not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

---

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)