APR - 6 2004

510(k) Summary
HRV Tools

January 12, 2004

1. Submitter Information

Name: Del Mar Reynolds Medical Ltd.

Address:

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ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
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Date Prepared: January 12, 2004

2. Name of Device

Trade Name:	HRV Tools
Common Name:	Heart Rate Variability Analysis Program
Classification name:	Computers and Software, Medical

3. Equivalent legally-marketed devices.

- Marquette Mars Unity workstation with heart rate variability, K991786 (includes frequency-domain)
- Medical Predictive Science Corporation HERO, K021230

4. Description

HRV Tools is a software product (supplied on a CD) that analyzes the basic rhythms of the RR intervals in electrocardiograms, both in the time domain (analysis of time intervals) and in the frequency domain (spectral analysis).

5. Intended Use

HRV Tools is a software product intended to analyze the basic rhythms of the RR intervals in electrocardiograms, both in the time domain (analysis of time intervals) and in the frequency domain (spectral analysis). It only provides numerical analyses of the input electrocardiogram – the program does not make diagnoses.

6. Performance Data

(a) Non-clinical tests

1. Tests with input data from the MIT database
2. Validation tests
3. Tests to check the operation of the algorithms
4. Accuracy tests

(b) Clinical tests

Clinical tests are not necessary since HRV Tools uses the same technology as the predicate devices.

(c) Conclusions

HRV Tools is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Del Mar Reynolds, Ltd.
c/o George H. Myers, Sc.D.
Official Correspondent
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K040313
Trade Name: HRV Tools
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: January 12, 2004
Received: February 09, 2004

Dear Dr. Myers:

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.

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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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510(k) Number (if known): K040313

Indications for Use Form

Device Name: HRV Tools

Indications for Use:

HRV Tools is indicated when it is desired to analyze the basic rhythms of the R-R intervals in electrocardiograms. It only provides numerical analyses of the input electrocardiogram – the program does not make diagnoses

Prescription Use X **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) number K040313