Traditional 510(k)
Summary

The following information is being submitted in conformance with 21 CFR 807.87(h):

1. **Submitter's Name:** Medical Monitors Limited
   Submitter's Address: Suite 407, Westfield Office Tower
   Eastgardens NSW 2036
   Australia

2. **Contact Person:** Harry L. Platt
   Telephone: +61 2 9344 8100
   Fax: +61 2 9344 8200
   Email: hplatt@medmon.com.au

3. **Date Prepared:** 6th January 2003

4. **Classification Name:** Telephone electrocardiograph transmitter and receiver

5. **Common Name:** Transtelephonic ECG Event Recorder

6. **Proprietary Name:** PER
   Model Number: Memo

7. **Product Code:** DXH

8. **C.F.R. Section:** 870.2920

9. **Classification:** Class II - Performance Standards

10. **Classification Panel:** Cardiovascular

11. **Device Description:**

The PER is a battery operated transtelephonic ECG event recorder and transmitter that is capable of storing multiple electrocardiograms and the transmission of these recordings by telephone to a receiving system. The PER stores the ECG before and after the 'record' button is depressed. The recording period is preset up to 80 seconds with 2 recordings stored. The stored ECGs are transmitted by acoustic output by coupling the telephone mouthpiece over the PER

12. **Intended Use:**

The PER is indicated for use by patients as directed by a physician, who experience transient symptoms that may suggest cardiac arrhythmia, conduction abnormalities or other rhythm disturbances that may result in shortness of breath, pre-syncope or palpitations.

13. **Establishment Registration Number:** 9618016

14. **Substantial Equivalence:** Legally marketed predicate device

510(k) NUMBER	PRODUCT	MANUFACTURER
K920984	KING OF HEARTS® EXPRESS	INSTROMEDIX, INC

15. **Comparison of Electrical Characteristics and Data Transmission**

The main electrical and transmission characteristics of the predicate device, KING OF HEARTS® EXPRESS (K920984), were compared to the PER Recorder ('PER- Characteristics Comparison and Transmission Validation' is appended). A specification comparison chart is also appended indicating the device similarities and equivalence.

The results of data transmissions and the measurements of the main functional characteristics of PER Transtelephonic ECG Recorder, when compared to the KING OF HEARTS® EXPRESS (K920984), indicate that the PER is substantially equivalent and gave better performance results for a number of key characteristics.

16. **Summary of Safety:**

The PER has been tested in accordance with the requirements of the following safety, EMC and device standards:

Australian Standard	International Standard	Description
AS 3200.1	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
AS 3200.1.1	IEC 60601-1-A1	Amendment 1 to Medical electrical equipment - Part 1: General requirements for safety
AS 3200.1.2	IEC 60601-1-2	Electromagnetic compatibility (EMC)
AS 2064.1	CISPR 11:1997 IEC 55011	Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment
-	AAMI EC11:1991	Diagnostic electrocardiographic devices

Electrical safety and EMC testing was performed on the PER in accordance with the requirements the above listed standards. In addition, testing was performed, where applicable, in accordance with AAMI EC11:1991.

The PER meets the set requirements and is in compliance for this device type.

17. **Risk Analysis:**

A risk analysis is appended (Risk Analysis – PER Transtelephonic ECG Recorder). The analysis identifies possible failure modes. For failure modes considered to be of medium or high probability of occurrence, system design

features and procedures used to mitigate the associated hazard are listed. For failure modes considered being of low probability, reasons for low probability estimates are given.

18. **Precautions:**

The PER has no known contraindications, however, it should be used in accordance with the instructions as indicated in the PER User Manual or as directed by a physician.

19. **Regulatory Approvals:**

The PER has the following regulatory approvals:

Australian Therapeutic Goods Listing - AUST L60797
Australian Communications Authority C-Tick – N3769

20. **Labeling:**

The PER labels appended are in conformance with 21 CFR 801 (Labeling)
(i) Key sheet label
(ii) Serial number label

21. **Additional Support Documents:**

Included here to support our claims for the safety and efficacy of the PER are the following additional documents:

(i) Predicate Device Specification Comparison Chart
(ii) Truthful and Accurate Statement
(iii) 510(K) Statement
(iv) Indications for Use Statement
(v) Image of the PER
(vi) PER Front Panel Keysheet
(vii) PER Back Panel Serial Number Label and Setup Label
(viii) Australian Therapeutic Goods Administration Listing
(ix) PER Characteristics Comparison & Transmission Validation
(x) PER Risk Analysis
(xi) PER User Manual
(xii) PER Patient Guide

22. **Conclusion - Safety and Effectiveness:**

The PER utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate device, the PER indicated no adverse indications or results.

It is our determination that the PER is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2003

Medical Monitors Limited
c/o Mr. Harry L. Platt
Executive Director
Suite 407, Westfield Office Tower
Eastgardens NSW 2036
Australia

Re: K030218
Trade Name: PER
Regulation Number: 21 CFR 870.2920
Regulation Name:
Regulatory Class: Class II (two)
Product Code: DXH
Dated: April 29, 2003
Received: May 2, 2003

Dear Mr. Platt:

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) 594-4646. 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

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Medical Monitors Limited

510(k) Number (if known):

Device Name: PER Memo

Indications For Use:

The PER is indicated for use by patients as directed by a physician, who experience transient symptoms that may suggest cardiac arrhythmia, conduction abnormalities or other rhythm disturbances that may result in shortness of breath, pre-syncope or palpitations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030218

Prescription Use Only

(Optional Format 1-2-96)