510(k) Summary

TAPUZ Medical Technology Ltd.

ECG Electrodes Apron

510(k) Number K 982470

Applicant's Name:

TAPUZ Medical Technology Ltd.
1 Alon Hatavor St.
Caesarea Industrial Park 38900, Israel

Contact Person:

Shoshana Friedman
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373, Israel
Tel: 972-9-771-8130
Fax: 972-9-771-8131

Date Prepared:

July 12, 1998

Trade Name:

ECG Electrodes Apron

Classification Name:

Electrocardiograph Electrodes

Classification:

The FDA has classified electrocardiograph electrodes as a class II device (product code 74 DRX) and it is reviewed by the Cardiovascular Devices Branch.

K982470

Indication for Use:

The ***ECG Electrodes Apron*** is a reusable electrode system intended for use in rest ECG recording. The ***ECG Electrodes Apron*** is compatible for use with most ECG instruments on the market.

Device Description:

The ***ECG Electrodes Apron*** is a system of ECG electrodes cast in a hyper-flexible silicone apron The electrodes are gold-plated and the conductors are made of copper. The entire apron, including the conductors, is flexible and can be stretched to fit all body shapes and sizes, men and women alike. The apron is connected by a standard cable and is compatible with almost any type of commonly used ECG instrument.

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.

Safety and Effectiveness:

The biological safety of the ***ECG Electrodes Apron*** has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility and verified through biocompatibility testing per ISO 10993-1.
The effective performance of the ***ECG Electrodes Apron*** has been established through comparative testing with market-cleared devices.

Substantial Equivalence:

The ***ECG Electrodes Apron*** is substantially equivalent to the Paljet-B (Golden Gate Bio-Device) cleared under K973663, the electrode set of the Mortara Model Eli 100 (Moratara Instruments) cleared under K920627, and the electrode set of the Cardiofax ECG 6551 (Nihon Kohden) cleared under K863116. Furthermore, in respect to performance, the ***ECG Electrodes Apron*** is substantial equivalent to most of the reusable electrode sets and may be connected to most of the ECG instruments on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1998

Akiva Sharon, M.D., M.Sc.
Managing Director
TAPUZ Medical Technology Ltd.
1 Alon Hatavor Street, P.O.B 3559
Caesarea Industrial Park 38900
ISRAEL

Re: K982470
ECG Electrodes Apron
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: July 12, 1998
Received: July 16, 1998

Dear Dr. Sharon:

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 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). 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 (Premarket 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"(21CFR 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/dsma/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

INDICATIONS FOR USE

510(k) Number (if known): K982470

Device Name: *ECG Electrodes Apron*

Indications for Use: The ***ECG Electrodes Apron*** is a reusable electrode system intended for use in rest ECG recording. The ***ECG Electrodes Apron*** is compatible for use with most ECG instruments on the market.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982470

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)