

NOV 12 2003

510(K) SUMMARY

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ITAMAR MEDICAL

510(k) Number K032519

Applicant's Name:

Itamar Medical Ltd.
2 Haeshel St., P.O.Box 3579
Caesarea 38900, Israel
Tel + 972 4 6177000
Fax + 972 4 6275598
e-mail: itamar-medical.com

Contact Person:

Dorit Winitz, Ph. D.
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
Tel: (972) 9 771-8130
Fax: (972) 9 771-8131
e-mail: dorit@push-med.com

Date Prepared:

August 2003

Trade Name:

Endo PAT 2000

Classification Name:

Programmable Diagnostic Computer

Classification:

Product Code: 74 DQK
Regulation No: 870.1425
Class: II
Panel: Cardiovascular

Predicate Device:

- PAT 1000 RD (Itamar Medical Ltd.), cleared under K001852
- Standard Procedures used for Endothelial Dysfunction evaluation:
 - The Intra-coronary Acetylcholine (Ach) Challenge method ("Gold Standard")
 - The method of Flow Mediated Dilation (FMD) response to reactive hyperemia of the brachial artery

Performance Standards:

No performance standards have been established for such a device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Endo PAT 2000 complies with the following voluntary standards:

- IEC 60601-1:1988+A1:1991+A2:1995
- IEC 60601-1-2:1993

Intended Use / Indications for Use:

The Endo PAT 2000 device is a non-invasive device, intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.

The Endo PAT 2000 has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals

The Endo PAT 2000 device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

Device Description:

The Endo PAT 2000 consists of a main control unit, finger probes and tubing and a software package. The Endo PAT 2000 main control unit is connected to two independent, thimble-shaped, finger mountable probes via two air-conducting tubes. A standard PC or Laptop is connected to the Endo PAT 2000 main control unit for on line display and archiving of device recordings and off line analysis. The output of the Endo PAT 2000 probe are pressure fluctuations sensed at its distal compartment induced by the volume changes of the pulsating digital arteries.

The Endo PAT 2000 system consists of two separate platforms connected by RS-232 channels:

- A PC platform running the custom “Endo PAT 2000 application program”
- An Endo PAT 2000 Main Control Unit with a micro-controller (8257) running a custom embedded program

Clinical Study:

The safety and effectiveness of the Endo PAT 2000 as an aiding tool in the diagnosis of coronary artery Endothelial Dysfunction were evaluated versus a Gold Standard for Endothelial Dysfunction evaluation, the Intracoronary Acetylcholine (Ach) Challenge method.

The reference method is an Intra-coronary procedure, which incorporates measurements of endothelium-dependent and endothelium-independent coronary flow reserve, calculated as the percentage change in coronary blood flow (CBF) and coronary artery diameter (CAD) in response to the Ach challenge.

Study population included intent to treat patients, who had been referred to the cardiac catheterization laboratory for diagnostic angiography secondary to signs or symptoms of ischemic heart disease and suspected coronary endothelial dysfunction, but who showed no angiographic evidence of obstructive coronary artery disease, and who underwent Intra-Coronary Acetylcholine (Ach) challenge test.

Patients were then evaluated using the Endo PAT 2000, which measures Peripheral Arterial Tone (PAT) changes at the fingertip, to a reactive hyperemia challenge.

Study results demonstrate that the Endo-PAT2000 is safe and effective for its intended use, as a statistical analysis of the study results showed acceptable sensitivity and specificity in a comparative study to a Gold Standard procedure, and no adverse events related to the device were reported.

Substantial Equivalence:

Itamar Medical Ltd. believes that, based on verification, validations, and safety and performance testing results, the Endo PAT 2000 device is substantially equivalent to its predicate device and to the standard procedures cited above without raising new safety and/or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Itamar Medical, Ltd.
c/o Dorit Winitz, Ph.D.
Project Manager
Push-med Ltd.
117 Ahuzah Street
Ra' ananna 43373
ISRAEL

Re: K032519

Trade Name: Endo PAT 2000
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 13, 2003
Received: August 15, 2003

Dear Dr. Winitz:

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 – Dorit Winitz, Ph.D.

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,


for 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

510(k) Number (if K032519 known): _____

Device Name: Endo PAT 2000

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

510(k) Number Division of Cardiovascular Devices

510(k) Number K032519

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