

510(K) SUMMARY FOR
MEDICARD LTD.
VGF-7 Vascular Graft Flowmeter

1. Date this summary was prepared: August 22, 1997

2. Submitter's Name and Address

Medicard Ltd.
P. O. Box 250
Upper Yoqneam 20692, Israel

3. Contact Person

Mr. Peter Dartal

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4. Device Name

Trade/Proprietary Name: VGF-7 Vascular Graft Flowmeter

Common Name: Graft Flowmeter

Classification Names: Cardiovascular blood flowmeter

5. Predicate Devices

The legally marketed devices to which equivalence is being claimed are:

- Model FM701D Cliniflow® II manufactured by Carolina Medical Electronics, Inc.
- Transonic Flowmeter manufactured by Transonic Systems, Inc.
- Vessel Cannula #30003 manufactured by the D L P Inc.

6. Device Description

The VGF-7 consists of an automatic syringe that injects blood or saline solution into proximal end of the vein graft at a controlled physiological pressure. The resulting flow rate is displayed on a digital readout.

The system consists of a servo mechanism controlled by a microprocessor. The microprocessor activates a controlled pressure loop to maintain a predetermined pressure of liquid in a syringe during injection. The liquid is injected from the syringe through a PVC tube and small graft cannula into the graft. The flowrate is the outcome of the liquid pressure and the graft flow resistance.

7. Intended Use

The VGF-7 Vascular Graft Flowmeter is device for measuring the flow of saline or other fluid through a graft when driven by a constant steady pressure or a controlled pulsatile pressure. It is indicated during coronary artery bypass surgery for assisting the surgeon in intra-operatively assessing the ability of a given vein graft preparation to support fluid flow.

8. Comparison of Technological Characteristics

The VGF-7 Vascular Graft Flowmeter works by injecting blood or saline into the graft at a controlled pressure and measuring the resultant flow. The Carolina Cliniflow® II works by generating a varying magnetic field in the blood vessel and measuring the electromotive force induced by the motion of the blood. This EMF is proportional to the strength of the magnetic field, the velocity of the flow, and the diameter of the vessel. The Transonic Medical Flowmeter works according to a proprietary "Ultrasound Transit-Time Technology."

9. Nonclinical Tests Used in Determination of Substantial Equivalence

The design of the Vein Graft Flowmeter has been thoroughly verified at the unit and system level. Non-clinical tests were conducted to validate the accuracy of flow determinations over the specified range of flows. The VGF-7 Vascular Graft Flowmeter has been tested to the electrical safety requirements and the Electromagnetic Compatibility requirements of EN 60601.

10. Conclusions From Nonclinical Testing

The testing of the VGF-7 Vascular Graft Flowmeter demonstrates that the performance is substantially equivalent to the predicate devices cited above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medicard, Ltd.
c/o Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultant, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K973198
Medicard VGF-7 Vascular Graft Flowmeter
Regulatory Class: II
Product Code: DPW
Dated: July 16, 1998
Received: July 17, 1998

Dear Ms. McNamara-Cullinane:

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.

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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" (21 CFR 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

510(k) Number (if known): K973198

Device Name: VGF-7 Vascular Graft Flowmeter

Indications For Use:

The VGF-7 Vascular Graft Flowmeter is indicated during artery bypass and other blood vessel surgeries for assisting the surgeon in intra-operatively assessing the ability of a given graft preparation to support fluid flow.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shankar B.L.

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K973198

Prescription Use ✓
(Per 21 CAR 801.109)

OR

Over-The-Counter Use _____