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K 041313
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MTC *Media Trade Corporation*

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510(k) Summary

Submitter's Name:	Guenter Ginsberg Media Trade Corporation
Address:	11820 Red Hibiscus Drive Bonita Springs, FL 34135
Phone:	(239) 948-2001
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E-mail:	mediatradecorp@gmx.net
Contact:	Guenter Ginsberg
Date of Summary:	May 7, 2004
Trade Name:	**Stabil-O-Graph,** Blood Pressure Monitor
Classification:	Noninvasive Blood Pressure Measurement System Product Code: DXN Regulation Number: 21 CFR 870.1130 Class: II
Predicate Devices:	OMRON, Model HEM-711 (773AC) K 021862 (Predicate)

Device Description:	The **Stabil-O-Graph** Blood Pressure Monitor is a fully automatic table model device that measures blood pressure in a human being by means of an inflatable cuff on the upper arm. It employs the method of the **"Oscillometric Principle"**.
Intended Use:	The **Stabil-O-Graph** Blood Pressure Monitor is intended to be used by adults at home to measure blood pressure (systolic and diastolic) and pulse rate from the upper arm.
Technological Characteristics:	The **Stabil-O-Graph** Blood Pressure Monitor has the same general design and performance characteristics as the predicate devices from Omron. The main difference is the physical size, shape and weight. The **Stabil-O-Graph** Blood Pressure Monitor has the same intended use, general design and incorporates similar materials and components, hence should therefore raise no new questions of safety and effectiveness. This submitter concludes that the **Stabil-O-Graph** Blood Pressure Monitor is therefore substantially equivalent to the predicate device from Omron.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2004

I.E.M. GMBH
c/o Mr. Guenter Ginsberg
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135

Re: K041313
Trade Name: I.E.M. Stabil-O-Graph
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 07, 2004
Received: May 17, 2004

Dear Mr. Ginsberg:

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,

Donna R. Vochmer

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

Enclosure

K041313

510(k) NUMBER (IF KNOWN): K041313

DEVICE NAME: I.E.M. Stabil-O-Graph

INDICATIONS FOR USE:

The I.E.M. **Stabil-O-Graph** is intended to be used by adults at home to monitor Blood Pressure (systolic and diastolic) and pulse rate from the upper arm with arm circumference ranging from 9.4 inches to 16.5 inches (24 cm to 42 cm).

Prescription Use _____ (Per 21 CFR 801.109) OR Over-The-Counter-Use X (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Bachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041313