K053395

DEC 2 3 2005

510(k) Summary

Submitter's Name:	**Card Guard Scientific Survival Ltd.,**
Address	2 Pekeris St. P.O.B. 527 Rehovot 76100, Israel
Phone:	972-8-9484019
Fax:	972-8-9484005
E-mail:	galex@cardguard.com
Contact:	**Alex Gonorovsky, RA Manager**
Date of Summary:	
Trade Name:	Blood Pressure Monitor
Classification:	Noninvasive Blood Pressure Measurement System Product Code: DXN Regulation Number: 21 CFR 870.1130 Class: II
Predicate Devices:	k041313 **Stabil-O-Graph**, Blood Pressure Monitor by I.E.M.
Device Description:	The **BP Pro** Blood Pressure Monitor is a fully automatic table model device that measures blood pressure by means of an inflatable cuff on the upper arm. It employs the **Oscillometric Principle.**
Intended Use:	The **BP Pro** 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 **BP Pro** Blood Pressure Monitor is identical to the predicate I.E.M. device except for its name, hence it should raise no new questions of safety and effectiveness. This submitter concludes that the **BP Pro** Blood Pressure Monitor is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2005

Card Guard Scientific Survival, Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pefris St. P.O.B. 527
Rehovot 76100
ISRAEL

Re: K053395
Trade Name: BP Pro Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 14, 2005
Received: November 16, 2005

Dear Mr. Gonorovsky:

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

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 (240) 276-0120. 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/industry/support/index.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

510(k) Number (if known): K053395
Device Name: BP Pro Blood Pressure Monitor

Indications for Use:

BP Pro 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 _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use [X] (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram D Zuckerman M.D.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053395

(Posted November 13, 2003)