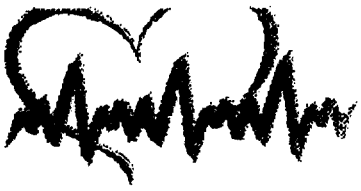


510(k) Summary

Lev-El, Ltd.'s HeartTrends™

510(k) Number K012825

MAR 1 9 2002

Applicant's Name:

Lev-El, Ltd.
P.O.B 3 Ariel
Israel 44837

Contact Person:

Avner Ben-Harush
Lev-El, Ltd.
P.O.B 3 Ariel
Israel 44837
Telephone: 972-3-9367489
Fax: 972-3-9060472

Date Prepared:

15 August 2001

Trade Name:

HeartTrends™

Classification Name:

Programmable Diagnostic Computer

Classification:

The FDA has classified Programmable Diagnostic Computer devices as class II device (product code DQK) and it is reviewed by the Cardiovascular Advisory Committee.

Predicate Devices:

The HeartTrends™ is substantially equivalent to the Biosensor Corporation Ambulatory (Holter) Recording System cleared under K950944.

Performance Standards:

The HeartTrends ™ complies with the following standards and regulations: cGMP/QSR, MDD 93/42 EEC (1993), ISO 9001 (1994), EN 46002 (1996), EN 60601-1-4 (1997), EN 1441 (1998).

Indication for Use:

The HeartTrends™ software is intended for the analysis, summary and reporting of up to 3 channels of prerecorded ambulatory ECG data.
It is also intended to provide measurements of the MPW (Multipole Paramater Weighted) HRV.

Device Description:

The HeartTrends™ software is employed as a measuring tool to present Heart Rate Variability (HRV) to qualified clinician review, edit and assessment.
It provides measurements of the MPW (Multipole Paramater Weighted) HRV.
The HeartTrends™ software is based on an algorithm, which is constructed from the Multipole method, based on a physical-mathematical description of complex time series.
The multipole method generates several parameters, multipoles, where every single one describes the HRV.

Substantial Equivalence:

Lev-El Ltd. believes that the HeartTrends™ is substantially equivalent to the Biosensor Corporation Ambulatory (Holter) Recording System cleared under K950944 in respect to intended use, technological characteristics, performance, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2002

Lev-El, Ltd.
c/o Ms. Einat Shammai
Arazy Group
Mizpe Aviv Industrial Park 13
M.P. Misgav, 20187
ISRAEL

Re: K012825
Trade Name: HeartTrends™ Software, Version 1.0
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: December 16, 2001
Received: December 19, 2001

Dear Ms. Shammai:

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.

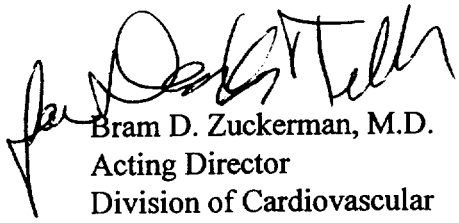
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K012825

Device Name: HeartTrends™

Indications for Use:

The HeartTrends™ software is intended for the analysis, summary and reporting of up to 3 channels of prerecorded ambulatory ECG data.
It is also intended to provide measurements of the MPW (Multipole Paramater Weighted) HRV.

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

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K012825