510(k) Summary

Lev-El, Ltd.'s HeartTrends™

510(k) Number K012825

MAR 1 9 2002

Applicant's Name:

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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.