

K950989

HELLIGE GMBH · Postfach 728 · D-79007 Freiburg i. Br.

MAY 13 1996

HELLIGE GMBH
 Munzinger Str. 3
 D-79111 Freiburg im Breisgau
 Germany
 Phone (0761) 4543-0
 Telex 7 72 705

Section 2 - Summary & Certification

Date 02-24-1995

2.1 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter HELLIGE GmbH
 Munzinger Str. 3
 79111 Freiburg, Germany
 Telephone +49-761-4534-0
 Fax +49-761-4543-223
 Contact person: Mr. Klaus Rudolf

Date February 24, 1995

Device Trade name: CardioSmart
 Classification name: Electrocardiograph;
 Detector and Alarm, Arrhythmia

Predicate Device HELLIGE CARDIOGNOST EK 56

Device Description CardioSmart is a portable ECG data acquisition and recording system designed and manufactured by HELLIGE GmbH.

CardioSmart allows to

- record resting ECGs,
- measure and interpret the ECGs.

Intended Use CardioSmart is intended to be used for resting ECG and for recording ECG in realtime with and without arrhythmia detection.

- CardioSmart is intended to be used by trained operators when ECG records are required in the judgement of a physician.
- The arrhythmia detection portion of CardioSmart is provided to the user for the convenience of automatic documentation.

Commerzbank AG Freiburg	BLZ 680 400 07	Kto.-Nr. 1400050.00
Dresdner Bank AG Freiburg	BLZ 680 800 30	Kto.-Nr. 4012483.00
Sparkasse Freiburg	BLZ 680 501 01	Kto.-Nr. 2006796
Volksbank Freiburg	BLZ 680 900 00	Kto.-Nr. 12191200
Postbank Karlsruhe	BLZ 660 100 75	Kto.-Nr. 52061-754
Landeszentralbank Freiburg	BLZ 680 000 00	Kto.-Nr. 6800735

Chairman of the board of directors:
 Peter P. Tong
 Managing director: Karl F. Braun
 HRB 3093 Freiburg im Breisgau

- CardioSmart does not provide alarms for arrhythmia detection.
- CardioSmart is not intended for use as a vital signs physiological monitor.
 - CardioSmart offers no diagnostic opinion to the user. Instead, it provides interpretive statements for which the physician renders his/her own medical opinion.
 - CardioSmart is not designed for intracardial use.
 - CardioSmart is not intended for home use.

The intended use of CardioSmart is a subset of the intended use of the predicate device. CardioSmart is a low cost alternative for all users who are not required to perform stress test ECGs.

Technology

CardioSmart basically employs the same technology as the predicate device.

All parts of the software which determine the medical functionality of the device were re-used from the predicate device.

The main differences between CardioSmart and the predicate device are

- lack of stress test,
- availability of a graphics displays with 3 traces,
- paper format B4,
- ECG storage function.

Performance / Standards

CardioSmart complies with the voluntary standards ANSI/AAMI EC11-1991, ANSI/AAMI ECAR-1987, IEC 601-1, IEC 601-1-2 and IEC 601-2-25.

CardioSmart passed the EC type-examination and thus bears the CE mark.

The following quality assurance measures were applied to the development of CardioSmart:

Requirements specification and design reviews, code inspections, software and hardware testing, safety testing, environmental testing, final validation testing by an independent test group, field tests.

The results of these measures demonstrated that CardioSmart is as safe, as effective, and performs as well as the predicate device CARDIOGNOST EK 56.

Signature:



Date:

24. Febr. 1995

Name:

Klaus Rudolf,
Manager Regulatory Affairs