5 510 (k) summary of Safety and Effectiveness

Date: August 7, 2003

Submitter:

ELA Medical, Inc.
2950 Xenium Lane North, Suite 120
Plymouth, MN 55441
Phone: (763) 519-9400
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Contact Person:

Susan Olive, Regulatory Affairs Manager

Device trade name:

SpiderView Holter ECG recorder

Common/usual name:

Ambulatory Holter Recorder

Classification name:

Electrocardiograph, Ambulatory (without analysis) MWJ (21 CFR 870.2800)

Predicate devices:

- Cardio ID+ (RZ153+) (K022540, ROZINN ELECTRONICS, INC.),

- Digitrak Plus (Philips) (K993617, Braemar Corp.),

- SyneFlash (K990727, ELA MEDICAL, INC) and SyneFlash MMC

Device description:

The SpiderView ™ Holter recorder is designed to acquire and store, in a digital format, multiple channels of surface ECG data (from 2 to 9 Leads) for a period up to 96 hours. The device stores the acquired ECG data on a removable flash memory card. ECG signals are converted at a rate of 200 to 1000 samples per second, which allows accurate reproduction of the ECG signal to perform signal averaging ECG analysis.

The Holter scanner software (sold separately) reads these data and prints them out in tabular or graphical form.

This recorder does not perform any analysis on the ECG data.

SpiderView™ is supplied in a case containing a 16, 32, or 64 MB flash-memory card, one 1.5 V AA battery, a carrying case, a strap, five patient cables, a set of ECG electrodes, and a user's manual.

Intended use:

The Spiderview Holter recorder is intended to perform ambulatory multi-channel ECG recording on pediatric or adult patients for periods up to 96 hours, and to perform high-

resolution recording of surface ECG data. It does not perform any analysis on the ECG data.

The SpiderView Holter recorder is intended to be used under the supervision of licensed and trained practitioners, in a hospital or clinic setting. Applications for Holter monitoring include, but are not limited to, evaluation of the following:

- Patient symptoms such as syncope, dizziness or palpitations
- Ischemia, especially in patients who cannot exercise or in patients with variant angina
- Function of an implanted pacemaker or defibrillator

Multi-day, multi-channel Spiderview recordings can be read and interpreted using Synescope Holter analysis software. Data collected on SpiderView using 2 to 3 channels and up to 24 hours can be read and interpreted using Synescope, Synetec or Syneview Holter analysis software.

Comparison of technology characteristics to predicate devices:

HOLTER RECORDER MODEL	SpiderView™	SYNEFLASH SYNEFLASH MMC	CARDIO ID+(RZ153+)	DIGITRAKPLUS
COMPANY	**ELA MEDICAL**	**ELA MEDICAL**	**ROZINN**	**BRAEMAR (sold by PHILIPS)**
510(k) Number	Present application	K990727	K022540	K993617
Type	Digital	Digital	Digital	Digital
Analysis	Retrospective (on the analyzer)	Real Time and Retrospective (on the analyzer)	Retrospective (on the analyzer)	Retrospective (on the analyzer)
Record duration	24H to 96H	24H	Up to 120H	Up to 48H
Recording medium	MMC or SD Flash card (16,32 64 MB)	PCMCIA FLASH CARD (10, 20, 40, 64MB) MMC or SD (16,32 64, 128MB)	CompactFlash Memory Card Type I or II	Internal Flash memory (non-removable)
Data transfer method	Via Removable memory card	Via Removable memory card	Via Removable memory card	Via USB port
Signal compression	Yes (delta + variable length bit coding = no notable loss)	Yes (delta + variable length bit coding = no notable loss)	No	No
CHANNELS	2, 3, 5, or 9 (the 5 channel recording authorizes true 9-lead ECG by calculation)	2 or 3	Multiple (2, 3, + true 12-Lead recording in option)	3 (+ EASI 12-Lead derived ECG)
Sampling rate	200sps	200sps	1024sps	175sps
Frequency Response	0.05Hz to 25Hz in standard mode 0.05Hz to 100Hz in no compression mode	0.05Hz to 25Hz in standard mode 0.05Hz to 80Hz in no compression mode	0.05Hz to 75Hz (0.05Hz to 150Hz in 12-Lead)	0.05Hz to 60Hz
Dynamic Range	+/-16 mV	+/-10 mV	+/-6mV	
	15 bit	12 bit	12 bit	10 bit
Amplitude Resolution	10µV (2.5µV in High Resolution mode)	10µV (2.5µV in High Resolution mode)	1.465µV	
High Resolution mode	Yes	Yes	No	No
High Resolution Sampling rate	1000sps	1000sps	NA	NA
High Resolution Transfer	Software utility to create a file in ISHNE format	Software utility to create a file in ISHNE format	NA	NA

HOLTER RECORDER MODEL	SpiderView™	SYNEFLASH SYNEFLASH MMC	CARDIO ID+(RZ153+)	DIGITRAKPLUS
Setup	With the graphic display + keyboard	With the graphic display + keyboard	With the graphic display + keyboard	With the graphic display + keyboard
ECG channel preview	Yes	Yes	Yes	Yes
CABLE	3, 5 or 7 wires	5 or 7 wires	7 or 10 wires	5 wires
Test Cable	Yes	Yes	Yes	No
Impedance measurement	Yes	Yes	Yes	Yes
POWER	1 AA 1.5V battery or 1 AA 1.2V NiMH rechargeable battery	2 AA 1.5V batteries or 2 AA 1.2V NiMH rechargeable batteries	1 or 2 AA 1.5V batteries Accept rechargeable batteries	1 AA 1.5V battery
Pacemaker Detection	Yes	Yes	Yes	Yes
DISPLAY	GRAPHIC LCD	GRAPHIC LCD	GRAPHIC LCD	LCD
Time Displayed	Yes (only during hookup)	Yes (only during hookup)	Yes	Yes
Carrying case	Belt + pouch	Belt + pouch	Belt + pouch	Belt + pouch
Keyboard	Yes	Yes	Yes	Yes
Sound	Yes (Buzzer)	Yes (Buzzer)	No	No
Patient event marker	Yes	Yes	Yes	Yes
On-board ECG analysis	No	Yes / Yes	No	No
Replay and Analysis system	SYNETEC, SYNEVIEW, SYNESCOPE for multi-lead and multi-day recordings	SYNETEC, SYNEVIEW	Holter for Windows®	Philips Holter analyzer
Weight	110g with batteries and flash card	290g with batteries and flash card	145g	100g
Dimensions	97x54x23mm	130x90x25mm	108x79x22mm	85x65x20mm

Summary of Studies

The following in-vitro functional testing was performed on the SpiderView™ Holter ECG recorder:

Test group	Tests
SpiderView™ safety testing	Environmental and safety tests, including EMC (Electromagnetic Compatibility) tests, according to the IEC 60601-2-47, IEC 60601-1-2 and ANSI/AAMI EC38-1998 standards.
SpiderView™ software validation and verification testing	Module and functional testing for SpiderView™ software applications

Conclusion

The information presented in this submission provides reasonable assurance that the SpiderView™ Holter ECG recorder will perform in a safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2003

ELA Medical, Inc.
c/o Ms. Susan J. Olive
Regulatory Affairs Manager
2950 Xenium Lane North, Suite 120
Plymouth, MN 55441

Re: K032466
Trade Name: Spiderview
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: August 8, 2003
Received: August 11, 2003

Dear Ms. Olive:

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,

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

Enclosure

510(k) Number (if known): K032466

Device Name: ELA Medical Spiderview Holter ECG Recorder

Indications For Use:

- Recording of up to nine-channel surface ECG (Electrocardiogram) data from ambulatory patients during a 96-hour maximum period.
- High-resolution recording of surface ECG data.
- Note: Analysis of recorded Holter ECG data requires separately-supplied ELA Synetec, Syneview, or Synescope Holter analysis software.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032464

(Optional Format 3-10-98)