NOV 26 1999

2. Summary & Certification

2.1 Summary of safety and effectiveness information

2.1.1 General Information

Device Generic Name: Holter ECG system (recorder and analysis software)

Device Trade Name: Syneflash™ (recorder) and Syneview™ (analysis software)

Applicant's Name and Address: ELA Medical, Inc., 2950 Xenium Lane North, Plymouth, MN 55441, Tel. (612) 519-9400

Date of Summary Preparation: February 26, 1999

Contact Person: Cathy G. Goble

510(k) Number: K990727

Date of Judgment of Substantial Equivalence Sent to Applicant:

Predicate Devices:

For Syneflash™: BURDICK ALTAIR Disc recorder (510(k) K942565, Burdick Inc.), BRAEMAR DL700 (510(k) K945130, Braemar Inc.) and OXFORD MEDILOG FD4 (510(k) K970902, Oxford Instruments).

For Syneview™: ELA Medical ELATEC (510(k) K895806, ELA Medical Inc.), BURDICK ALTAIR 8200 (510(k) K945985, Burdick Inc.) and REYNOLDS Pathfinder 700 (510(k) K951902, Reynolds Medical Ltd.).

2.1.2 Description of Conditions for Which the Devices are Indicated

Generally accepted indications for Holter ECG systems include:

- Recording of two- or three-channel surface ECG (Electrocardiogram) data from ambulatory patients during a 24-hour period.
- High-resolution recording of surface ECG data.
- Analysis of recorded Holter ECG data.

2.1.3 Device Description

Syneflash™ is a light-weight digital ambulatory electrocardiogram (ECG) recorder (Holter monitor) equipped with a graphic LCD screen, and using a flash-memory card

for data storage. It allows 24-hour ambulatory ECG recording and high-resolution recording, using 2 or 3 channels.

Syneflash™ is supplied in a case containing a 10-, 20- or 40-MB flash-memory card, two 1.5-V AA batteries, a carrying case, a strap, a five-lead (or seven-lead) patient cable and a user's manual.

Syneview™ is a Holter ECG analysis software application that allows evaluation of Holter recordings obtained with Syneflash™. Syneview™ is a Microsoft Windows95/98-based application run on an IBM-compatible personal computer equipped with a flash-card reader.

2.1.4 Comparison to predicate devices

Comparison table between ELA MEDICAL SYNEFLASH and predicate recorders:

HOLTER RECORDER MODEL	SYNEFLASH	MEDILOG FD4	ALTAIR-DISC RECORDER	DL 700
COMPANY	ELA MEDICAL	OXFORD INSTRUMENTS MEDICAL SYSTEMS	BURDICK	BRAEMAR
510(k) Number		K970902	K942565	K945130
CE mark (93/42 MDD)	Yes	No		
Type	Digital	Digital	Digital	Digital
Analysis	Real Time	Retrospective (on the analyzer)	Retrospective (on the analyzer)	Retrospective (on the analyzer)
Record duration	24H	24H	24H	24H
Recording medium	PCMCIA FLASH CARD (10, 20 40 MB)	PCMCIA FLASH CARD (ATA)	Hard disk (170MB)	PCMCIA ATA FLASH CARD (10, 20 40 MB)
Signal compression	Yes (delta + variable length bit coding = no notable loss)	Yes	No	Yes
CHANNELS	2 or 3	2 or 3	2 or 3	2 or 3
Sampling Frequency	200Hz	512Hz	200Hz	128Hz
Frequency Response	0.05Hz to 50Hz in standard mode (extension to 500Hz possible in High Resolution mode)		0.05Hz to 100Hz in standard mode (extension to 300Hz possible in High Resolution mode)	
Overall Recorder/Analyzer Frequency Response	0.05Hz to 50Hz in standard mode	0,05Hz to 40Hz		
Dynamic Range	10µV to 10 mV	10µV to 10 mV	5mV in standard mode (10 mV in High Resolution mode)	
Amplitude Resolution	10µV (2.5µV in High Resolution mode)			

HOLTER RECORDER MODEL	SYNEFLASH	MEDILOG FD4	ALTAIR-DISC RECORDER	DL 700
High Resolution mode	Yes (Hi Res or Hi Res + Holter)	No	Yes (Hi Res or Hi Res + Holter)	No
High Resolution Sampling Frequency	1000Hz		1000Hz	
High Resolution Transfer	By a transferring utility Between Flash Card and PC		By connection to the PC with an interface.	
Setup	With the graphic display + keyboard	By connection to the PC with fiber optical cable		
Verification of the ECG	With the graphic display	By connection to the PC with fiber optical cable		
Test Cable / Impedance check	Yes / Yes			
CABLE	5 or 7 wires	3, 5 or 7 wires		
POWER	2AA 1.5V Alkaline Batteries (for 2x24H records) or 1x24H record with 1.2V NiMh rechargeable batteries (1200mA/H)	2AA 1.5V Alkaline Batteries or 1.2V NiMh rechargeable batteries	2 x 9V batteries	9V batteries
Pacemaker Detection	Yes	Yes	Yes	
DISPLAY	GRAPHIC LCD	4 digits (7 segments) LCD display	LCD	LCD
Time Displayed	Yes (only during hookup)	Yes	Yes	Yes
Carrying case	Strap + pouch	Strap + pouch		
Keyboard	Yes	Yes	Yes	No
ON/OFF Button	Yes	Yes		No
Sound	Yes (Buzzer)	Yes		
Patient event marker	Yes (resolution at sampling frequency)	Yes (resolution at sampling frequency)		Yes
Case	Polycarbonate / ABS	Polycarbonate / ABS		
Replay and Analysis system	SYNEVIEW	OXFORD OPTIMA & EXCEL	BURDICK ALTAIR 8200	REYNOLDS PATHFINDER 700 and others.
Weight	290g with batteries and flash card	310g with batteries and flash card	425g	
Dimensions	130x90x25mm	120x90x40mm	129x91x32mm	
HOLTER RECORDER MODEL	**SYNEFLASH**	**MEDILOG FD4**	**ALTAIR-DISC RECORDER**	**DL 700**

Operating temperature	0°C to 50°C	0°C to 45°C		
Storage temperature	-15°C to 60°C			
Humidity	85% (at 20°C)	10-95% non condensing		
Firmware Upgrade	Yes	Yes		

Comparison table between ELA MEDICAL SYNEVIEW and predicate analyzers:

HOLTER ANALYZER MODEL	**SYNEVIEW**	**ELATEC**	**ALTAIR 8200**	**PATHFINDER 700**
COMPANY	**ELA MEDICAL**	**ELA MEDICAL**	**BURDICK**	**REYNOLDS MEDICAL**
510(k) Number		K895806	K945985	K951902
CE / MDD certification	Yes	No		
Type	Holter Analyzer (Software)	Holter Analyzer	Holter Analyzer	Holter Analyzer
Read digital / tape	Digital (dedicated to SyneFlash recorder)	Standard 1mm/s tape (and 1,5mm/s, 2mm/s tape)	Digital (Burdick Disc recorder only) and Standard Tape	Digital (Braemar DL700, REYNOLDS eRAM) and Standard Tape
PC based	Yes	Yes	Yes	Yes (+transputer)
PCMCIA interface compatible	Yes	No	No	Yes
Operating System	Microsoft Windows 95 or 98	Microsoft DOS	Microsoft DOS	Microsoft DOS
Graphic User Interface (GUI)	Yes	Yes	Yes	Yes
Network	Yes	No		
Re-analysis	No	Yes	Yes	Yes
Events list edition	Yes	No	No	No
Arrhythmia detection	Yes	Yes	Yes	Yes
ST	Yes	Yes	Yes	Yes
Templates screen	Yes	Yes	Yes	Yes
Superimposition	Yes	Yes	Yes	Yes
Pacemaker detection	Yes	Yes	Yes	Yes
Editing report	Yes	Yes	Yes	Yes
Customized report	Yes	Yes	Yes	Yes
Archiving	Yes	Yes	Yes	Yes
Printing ECG strip	Yes	Yes	Yes	Yes
Printing Full Disclosure	Yes	Yes	Yes	Yes

2.1.5 Alternatives

The alternatives for Syneflash™ and Syneview™ are other commercially available Holter ECG systems.

2.1.6 Marketing History

Syneflash™ and Syneview™ are not in commercial distribution in the U.S. They were recently introduced into commercial distribution outside the U.S (April 1997 for Syneview™, March 1998 for Syneflash™). No unanticipated adverse device effects have been reported for this Holter ECG system.

2.1.7 Potential Adverse Effects

As Holter ECG systems are diagnostic devices, there are no potential adverse effects or complications related to this type of device.

2.1.8 Summary of Studies

The following in-vitro functional testing was performed on the Syneflash™ / Syneview™ Holter ECG system:

Test group	Tests
Syneflash™ safety testing	Environmental and safety tests, including EMC (Electromagnetic Compatibility) tests, according to the EN 60601-1, EN 60601-1-2 and ANSI/AAMI EC38-1994 standards
Syneview™ database testing	Database testing according to the ANSI/AAMI EC38-1994 standard using the following databases: • AHA (American Heart Association), • MIT (Massachusetts Institute of Technology), • ST (European database on ST segment) • NST (Noise Stress Test)
Syneflash™ / Syneview™ software validation and verification testing	Unit and functional testing for both Syneflash™ and Syneview™ software applications

2.1.9 Conclusion

The information presented in this submission provides reasonable assurance that the Syneflash™ / Syneview™ Holter ECG system 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

NOV 26 1999

Ms. Catherine G. Goble
ELA Medical, Inc.
2950 Xenium Lane North
Plymouth, MN 55441

Re: K990727
Syneflash™ and Syneview™ Holter ECG System
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: October 25, 1999
Received: October 26, 1999

Dear Ms. Goble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990727

1.10 Indications for Use Statement

510 (k) Number:

Device Name: Syneflash™ / Syneview™ Holter ECG system.

Indications for Use:

- Recording of two- or three-channel surface ECG (Electrocardiogram) data from ambulatory patients during a 24-hour period.
- High-resolution recording of surface ECG data.
- Analysis of recorded Holter ECG data.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Carey

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990727

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)