K970072

AUG 29 1997

Summary & Certification

Summary of safety and effectiveness information

General Information

Device Generic Name: Single chamber, SSI pacemaker.

Device Trade Name: Opus S Model 4121 and 4124 pacemakers

Applicant's Name and Address: ELA Medical, Inc., 2950 Xenium Lane N., Suite 120, Plymouth, MN 55441, Tel. (612) 519-9400

Date of Summary Preparation: October 21st, 1996

Contact Person: Catherine G. Goble

510(k) Number: K970072

Date of Judgment of Substantial Equivalence Sent to Applicant:

Predicate Devices: ELA Medical Opus Model 4021 (510(k) K900461 and K952363, ELA Medical Inc.) and 4024 pacemakers (510(k) K882391 and K952364, ELA Medical Inc.).

Description of Conditions for Which the Devices are Indicated

Generally accepted indications for long-term single-chamber cardiac pacing include:

- AV conduction disorders or intraventricular paroxysmal/permanent conduction disorders with permanent atrial tachycardia: atrial fibrillation or flutter (lead implanted in the ventricle),
- Sinus bradycardia, sinoatrial block, brady-tachy syndrome without atrioventricular conduction disorder (lead implanted in the atrium).

Device Description

Opus S, Model 4121 and 4124 are single-chamber programmable pacemakers with the following specifications:

Programmable parameters:

Basic parameters:

Mode: ***SSI***, SST, SOO

Basic rate (ppm): 30, 40, 45, 50, 55, 60, 65, ***70***, 75, 80, 85, 89, 96

Maximum rate (ppm): 101, 110, ***120***, 132, 142, 154

Hysteresis (% of rate): ***0***, 5, 10, 20, 33

Absolute refractory period (ms): ***172***, 203, 234, 266, 297, 328, 359

Pacing and sensing:

Pulse amplitude (V): 1.5, 2.0, 2.5, 3.0, ***3.5***, 4.0, 5.0,

Pulse width (ms): 0.12, 0.24, 0.37, ***0.49***, 0.61, 0.73, 0.85, 98

Sensitivity (mV): 0.4, 0.6, 0.8, 1.0, 1.2, 1.5, 1.8, ***2.0***, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5

Polarity:

	Model 4121	Model 4124
Pacing	Unipolar	***Unipolar*** - Bipolar
Sensing	Unipolar	***Unipolar*** - Bipolar

Specific function:

Rate-smoothing (ms/8 cycles): 16, 31, 47, 63, 78, 94, ***OFF***

Non-programmable parameters

Rate limit: 170 ppm

Magnet rate: 96 ppm at BOL, 80 ppm at ERI

Technical specifications

	Model 4121	Model 4124
Dimensions (mm)	52.4 x 36.1 x 6.6	47.6 x 36.1 x 6.6
Weight (g)	25	25
Volume (cc)	9.9	9.4
Connections	Unipolar, 5.0-6.0 mm	Unipolar/bipolar, IS-1 3.2 mm
Battery	WG 8426, 0.94 Ah	WG 8426, 0.94 Ah
Longevity	6 years*	6 years*

* 100 % pacing, SSI, 70 ppm, 3.5 V, 0.49 ms, 500 Ω, 37 °C

Follow-up functions

Statistics:

Number and percentage of: paced cycles, sensed cycles, extrasystoles

Number of: cardiac cycles, programmings

Heart rate curve: 45 minutes, 24 hours, ***OFF***

Event markers: Identification of two event types: spontaneous and paced events

Intracardiac ECG

Threshold test: Programmable threshold test rate (ppm): 80, 89, ***101***, 110, 120

Lead measurement: Impedance, current, voltage, and energy

As shipped values shown in bold/italics

Physical characteristics

The electronic circuit and battery of Opus S Model 4121 and 4124 pacemakers are encapsulated in a hermetic titanium case. Pacing leads are connected through a medical grade silicone elastomer connector. The different functions of Opus S Model 4121 and 4124 pacemakers are assured by a hybrid circuit. The hybrid circuit is a substrate onto which different electronic components are mounted:

- passive components (resistors, capacitors, etc.) and
- integrated circuits (microprocessor and custom circuit).

Programmer system

The programmer system consists of:

- Programming head
- Programmer software
- IBM-compatible PC

Opus S Model 4121 and 4124 pacemakers are similar in design and construction to other single-chamber pacemakers in commercial distribution.

Comparison to predicate devices

ELA Medical Opus™ S Model 4121 and 4124 pacemakers are similar to the predicate Opus™ Model 4021 and 4024 pacemakers, respectively, except for these general differences. Physically, both Opus-S models are smaller to improve patient comfort. A smaller size was achieved by using a smaller (but widely used) battery, reducing the

connector size (without substantially altering its design) and making the hybrid smaller. Functionally, a few programmable parameter values were changed to make Opus S more flexible for managing patient conditions. Pacing and sensing polarity were also made independently programmable for Opus-S Model 4124 pacemaker (versus fixed for Opus models) to offer more flexibility to manage patient needs. Otherwise, the two Opus-S models are substantially equivalent to the two respective predicate Opus models. The programmer parameter value changes and programmable polarity were achieved by modifying the custom integrated circuit on the hybrid. The programmer system is similar to that of Opus™ Model 4021 and 4024.

Similar designs and manufacturing processes, and the same materials, are used to make the ELA Medical Model 4121, 4124, 4021 and 4024 pacemakers.

Alternatives

The alternatives for Opus S Model 4121 and 4124 pacemakers are other commercially available single-chamber, SSI pacemakers.

Marketing History

Opus S Model 4121 and 4124 pacemakers are not in commercial distribution in the U.S. They were recently introduced into commercial distribution outside the U.S. No unanticipated adverse device effects have been reported for these pacemakers.

Potential Adverse Effects

The potential adverse effects of Opus S Model 4121 and 4124 pacemakers are the same as those for single-chamber (SSI) pacemakers in commercial distribution. Pacemaker-related complications are described in the Opus S physician's manual.

Summary of Studies

The following in-vitro functional testing was performed on the Opus S Model 4121 and 4124 pacemakers:

Test group	Tests
Sterilization Process Validation	• ETO sterilization process validation • Mechanical qualification of sterilization process modification • Sterilization indicator qualification
Laser Welding Process Validation	
Pacemaker Environmental Performance Testing	• Baseline Electrical Performance • Thermal Shock • Mechanical Shock • Random Vibration • Vibration: Italian Requirements • Drop Tests (packaged and unpackaged devices)
Connector Testing (IS-1 and 5.0-6.0 mm)	• Electrical Isolation • Pacing Lead Insertion/Withdrawal Forces • Electrical Resistance • Rotation of Inserts • Perforation and Rupture Force

Test group	Tests
Feedthrough Testing	• Electrical Isolation Resistance • Hermeticity • Tensile Strength • Temperature Cycling • Aging
Mechanical Qualification of Packaging	• Bioburden • Visual Inspection • Hermeticity
Hybrid Testing	• Environmental • Temperature Cycling • Constant Acceleration • Vibration • Mechanical Shock • Seal Hermeticity • Particle Impact Noise Detection (PIND) • Final Electrical Test • Life (Reliability) Test
Die Attach Qualification	

Test group	Tests
Hybrid Component Testing	• Microprocessor • Ceramic and Tantalum capacitors • Resistor chip • Zener diode • Pacing chip
Pacemaker Interference Testing	• Protection Against Spurious Current Induced by Electromagnetic Interference • Protection Against Sensing Electromagnetic Interference • Protection Against Malfunction Due to Electromagnetic Interference • Protection Against Electrosurgery Current • Defibrillation Protection • Electrostatic Discharge Protection • Cellular Phone Interference
Software validation	• Implant software validation • Programmer software validation

Biocompatiblity testing was not performed, due to the successful history with the same materials in other pacemakers. Sterilization testing and mechanical / environmental packaging validation were performed, because the pacemaker package design and sterilization method changed. All test results demonstrated that the established pass / fail criterion was met in all cases.

Conclusion

The information presented in this submission provides reasonable assurance that the Opus S Model 4121 and 4124 pacemakers 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 29 1997

Ms. Catherine G. Goble
Regulatory Affairs Manger
Ela Medical
2950 Xenium Lane North
Plymouth, MN 55441

Re: K970072
Trade Name: Opus S Model 4121 and 4124 Single Chamber Pacemakers
Regulatory Class: III (3)
Product Code: DXY
Dated: August 20, 1997
Received: August 21, 1997

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 to 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) 594-4639. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510 (k) Number: K970072

Device Name: Opus S Model 4121 and 4124 pacemakers.

Indications for Use:

- AV conduction disorders or intraventricular paroxysmal/permanent conduction disorders with permanent atrial tachycardia: atrial fibrillation or flutter (lead implanted in the ventricle),
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Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970072

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)