K972574

JAN - 8 1998

2. Summary & Certification

2.1 Summary of safety and effectiveness information

2.1.1 General Information

Device Generic Name: Atrial tined pacing lead.

Device Trade Name: Stela™ Model UJ45 Pacing Lead

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

Date of Summary Preparation: June 27, 1997

Contact Person: Catherine G. Goble

510(k) Number:

Date of Judgment of Substantial Equivalence Sent to Applicant:

Predicate Devices: ELA Medical Focus® Model J43F unipolar tined silicone rubber pacing lead (Document Control Number K896742) and Stela™ Model BJ45 bipolar tined silicone rubber pacing lead(Document Control Number K963698).

2.1.2 Description of Conditions for Which the Devices are Indicated

The Stela™ Model UJ45 lead is indicated for cardiac pacing and sensing, which is the same as other transvenous tined leads.

2.1.3 Device Description

The Stela™ Model UJ45 is a silicone rubber, tined, J-shaped, unipolar transvenous lead that provides a permanent electrical pathway between a pacemaker and the atrium. It is similar in design and construction to other such leads in commercial distribution.

2.1.4 Alternatives

The alternatives for the Stela™ Model UJ45 lead are other commercially available transvenous pacing leads.

2.1.5 Marketing History

The Stela™ Model UJ45 lead is not in commercial distribution in the U.S. It was recently introduced into commercial distribution outside the U.S. No unanticipated adverse device effects have been reported for these leads.

2.1.6 Potential Adverse Effects

The potential adverse effects of Stela™ Model UJ45 leads are the same as those for tined, J-shaped, transvenous leads in commercial distribution. Lead-related complications are described in the ELA Medical generic lead manual.

2.1.7 Summary of Studies

The following in-vitro functional testing was performed on the Stela™ Model UJ45 leads:

- stylet insertion/removal
- stylet bottoming
- electrical resistance
- IS-1 connector conformity
- leak resistance
- insulation integrity
- tensile strength test.

Biocompatiblity testing was not performed, due to the successful history with the same materials in other lead products. No new sterilization testing or mechanical / environmental packaging validation were performed, because the lead package design and sterilization method did not change from the Stela™ Model BJ45.

No clinical study was required to demonstrate safety and effectiveness since the Stela™ Model UJ45 presents no new feature.

2.1.8 Conclusion

The information presented in this submission provides reasonable assurance that the Stela™ Model UJ45 lead 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 20856

Ms. Catherine G. Goble
Regulatory Affairs Manager
ELA Medical Inc.
2950 Xenium Lane North
Plymouth, Minnesota 55441

JAN - 8 1998

Re: K972574
Stela™ Model UJ45 Pacing Lead
Regulatory Class: III (three)
Product Code: 74 DTB
Dated: June 27, 1997
Received: July 10, 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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(A) the device cleared for marketing by this letter as requiring postmarket surveillance.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Room 3083 (HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete and FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

In addition, on August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirement of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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

Enclosures

1.10 Indications for Use Statement

510 (k) Number:

Device Name: Stela™ Model UJ45 pacing lead.

Indication for Use:

ELA Medical endocardial leads are designed to be used with implantable cardiac pacemakers.

J-shaped leads are intended for permanent pacing and sensing of the atrium.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972574

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)