3.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by	Synovis Interventional Solutions, Inc. 475 Apollo Drive Lino Lakes, MN 55014 Tel: 651-603-5229 Fax: 651-603-5211
Contact Person	James Jenkins Synovis Surgical Innovations 2575 University Avenue W. St. Paul, Minn. 55114-1024 Tel. 651-603-5229 or 651-796-7368 Fax 651-603-5211
Device Trade Name:	To be determined
Common Name	Catheter Stylet
Classification Name	Catheter Stylet 870.1380
Predicate device	The Locator Steerable Stylet, Model 4036 K972814 St. Jude Medical
Device Description	The Steerable Stylet is a sterile, single-use, disposable implantation tool which assists defining and varying the curvature of the distal portion of the pacemaker lead during implantation.
Statement of Intended use	The Steerable Stylet is intended to aid in the placement of pacemaker leads.
Technological Comparisons	The Steerable Stylet is substantially equivalent to the predicate device, having similar performance, technological characteristics, and indication for use.
Testing	The Steerable Stylet is substantially equivalent to the predicate device in terms of performance testing. Test results are included in submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Synovis Interventional Solutions, Inc.
c/o Mr. James Jenkins
Regulatory Affairs Specialist
2575 University Avenue
St. Paul, MN 55114-1024

Re: K040001
Trade Name: Steerable Stylet
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter Stylet
Regulatory Class: Class II (two)
Product Code: DRB
Dated: December 31, 2003
Received: January 2, 2004

Dear Mr. Jenkins:

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

Indications for Use

510(k) Number (if known): K040001

Device Name: Steerable Stylet

Indications For Use: The Steerable Stylet is intended to allow the physician to define and vary the curvature of the distal end of a compatible pacemaker lead in patients requiring lead implantation for cardiac pacing.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

sion Sign-Off)
sion of Cardiovascular Devices

k number K040001