

E. 510(k) SUMMARY (as required by 21 CFR 807.87(h))

Date Prepared: May 23, 1998

Sponsor: Boston Scientific Corporation
2710 Orchard Parkway
San Jose CA 95134
Telephone: (408) 895-3500
Contact: Steve.Jwanouskos
Title: Senior Director, Regulatory Affairs
and Quality Compliance

Trade Name: Boston Scientific Tissue Coagulation System
Common Name: Electrosurgical System
Classification Name: Electrosurgical cutting and coagulation device and accessories
Classification: Class II-21 CFR 878.4400
Predicate Devices: Vallev Lab Force 40, VNUS Medical Closure™ System, Somnus Medical Model 615, Oratec ORA-50™, Arthrocare Electrosurgery System, Wappler Electrosurgical Unit, Ximed Medical Electrode Probe, and Circon Surgical Instruments

Device Description: The Boston Scientific Tissue Coagulation System is comprised of an Electrosurgical Unit (ESU), Electrosurgical Probe, and accessories for the application of radiofrequency energy to tissue. The ESU supplies up to 150 watts of radiofrequency energy in unipolar mode to the electrodes of the Electrosurgical Probe under temperature control while continuously monitoring and displaying actual power delivered, actual electrode temperature, and time of power duration. User controls are provided for setting desired temperature, maximum power output, and duration of power delivery. ESU safety features include overvoltage, overcurrent, and overpower shutdowns.

Intended Use: The Boston Scientific Tissue Coagulation System is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Tissue Coagulation System may also be used to coagulate blood and soft tissues to produce hemostasis.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1998

Mr. Steve Jwanouskos
Senior Director, Regulatory Affairs
and Quality Compliance
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, California 95134

Re: K981981
Trade Name: Boston Scientific Tissue Coagulation System
Regulatory Class: II
Product Code: GEI
Dated: June 3, 1998
Received: June 5, 1998

Dear Mr. Jwanouskos:

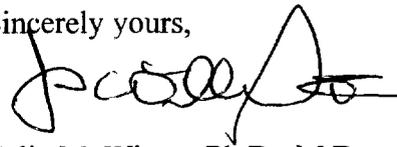
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, 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 requirement, 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) 594-4595. 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,



Celia M. Witten

fc Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K981981

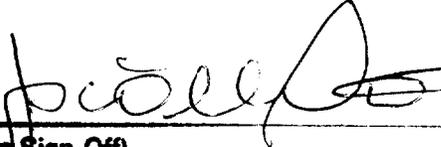
Device Name: Boston Scientific Tissue Coagulation System

Indication For Use:

The Boston Scientific Tissue Coagulation System is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Tissue Coagulation System may also be used to coagulate blood and soft tissues to produce hemostasis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981981

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)