Boston Scientific Corporation
100 Boston Scientific Way, Marlborough, MA 01752

510(k) Pre-Market Notification

SURGICAL MESH

K020110

January 9, 2002

EXHIBIT
8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 3 2002

Ms. Lorraine M. Hanley
Director
Global Regulatory Affairs
Boston Scientific/Urology
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K020110
Trade Name: Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: II
Product Code: FTL
Dated: January 9, 2002
Received: January 11, 2002

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Miriam C. Provost

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

Enclosure

IV. Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Surgical Mesh

Indications For Use:

It is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use (Optional Format 1-2-96)**

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K020110

Boston Scientific
MICROVASIVE

Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
www.bsci.com

January 9, 2002

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: **Original Abbreviated 510(k) Premarket Notification for the Surgical Mesh**

Dear Sirs/Madame;

Pursuant to 21 CFR 807.81, Boston Scientific / Urology, hereby submits three copies of this Abbreviated Premarket Notification for the **Surgical Mesh**, and three copies of this cover letter.

The purpose of this current 510(k) premarket notification is to introduce a modification to the Trelex Mesh (K945733) surgical mesh, which has been cleared for reinforcing soft tissue where weakness exists. The proposed device is also substantially equivalent to predicate devices intended for the treatment of stress urinary incontinence (SUI) resulting form urethral hypermobility and/or intrinsic sphincter deficiency. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension. All these predicate devices are classified in 21CFR 878.3300: Mesh, surgical, polymeric, product code FTL.

Boston Scientific has elected to notify its intent to market the proposed **Surgical Mesh** through an Abbreviated 510(k) submission. Section I of this document includes introductory information as suggested in the Guidance for the Preparation of a Premarket notification Application for Surgical Mesh, March 2, 1999. The "Summary of Safety and Effectiveness" is located in Section III, the "Statement of Intended Use" is in Section IV, and the " Truthful and Accuracy Statement" is located in Section V. The "Declaration of Conformity with Recognized Consensus Standards and Guidances" is provided in Section VI.

At this time, Boston Scientific is not aware that this device is subject to Section 522 of the Federal Food, Drug, and Cosmetic Act (The Act), i.e., Postmarket Surveillance. It is the understanding of Boston Scientific/ Urology that written notification will be received from FDA if this device is subject to section 522 of The Act.

The terms "substantially equivalent","similar", and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug, and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

Boston Scientific/Urology has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, Boston Scientific/ Urology considers its intent to manufacture this device for distribution under its own label to be confidential commercial information and exempt from public domain. Boston Scientific understands that data contained in this submission will be restricted from release under the Freedom of Information Act for at least 90 days or until concurrence is gained. To the best of our knowledge, conditions of confidentiality in 21CRF807.95 have been maintained.

If you have any questions about the Premarket Notification, please contact me at 508-650-8172.

Sincerely,

Lorraine M. Hanley

Lorraine M. Hanley
Director, Global Regulatory Affairs
Boston Scientific/ Urology
Telephone Number: (508) 650-8172
Fascimile: (508) 650-8144

Administrative Assistant: (508) 647-2573

II. Table of Contents

Exhibit VIII-1 Material Specifications

Exhibit VIII. Material Specifications

A. Resin CoA and MSDS
B. Monofilament Product Specification

Exhibit VIII. Material Specifications

A. Resin CoA and MSDS
B. Monofilament Product Specification

PHILLIPS CHEMICAL COMPANY
A DIVISION OF PHILLIPS PETROLEUM COMPANY
BOX 792 • PHONE: 713 475-3666
PASADENA, TEXAS 77501-0792

PHILLIPS PLASTICS RESINS
Houston Chemical Complex

April 02, 1997

JHV# 6636-97

FAX: 803-754-7991

Shakespeare Monofilament Co.
6111 Shakespeare Road
Columbia, SC 29223

Kenneth DuPree

This letter will certify that the Marlex* resin shown below, as supplied by Phillips Sumika Polypropylene Company, conforms to our manufacturing specification.

Shakespeare Part Number: 90094

Type:	HGX-030-01
Lot Number:	2971205
P.O. Number:	27376
Date Shipped:	04/01/97
Package:	BAG
Quantity:	44080 LBS.
Melt Flow:	3.5 G/10 MIN

J. H. Vaden
Quality Assurance Manager

For COA questions call Sharon Robinette, 713-475-3625

* Reg. U.S. Pat. Off.

cc: QA-File-RC
D. E. Powell

LOT APPROVED
FOR RELEASE TO
MANUFACTURING
By
Date 4/3/97

VIII-3

Marlex

HIGH PERFORMANCE POLYPROPYLENES

Marlex® HGX-030-01

Polypropylene Homopolymer, Fiber Grade, Low Water Carryover

Nominal Physical Properties (3)	ASTM Test Method	Traditional Units	SI Units
Density (1)	D1505	0.909 g/cc	909 Kg/m^3
Melt Flow, Condition 230 °C/2.16Kg	D1238	3.5 g/10 min	3.5 g/10 min
Tensile Yield Strength (2) *Type 1 Specimen, Rate: 2"/min*	D638	5,200 psi	36 MPa
Flexural Modulus Tangent (1) *Rate 0.5"/min*	D790	260,000 psi	1,792 MPa
Izod Impact Strength (2) Notched, at 73 °F (23 °C) Unnotched, at 73 °F (23 °C)	D256	0.5 ft*lbf/in No Break	27 J/m No Break
Heat Deflection Temperature (2) 66 psi (0.45 MPa) 264 psi (1.82 MPa)	D648	220 °F 150 °F	104 °C 66 °C
Hardness, Shore D (2)	D2240	74	74
Agency Information:	• Meets FDA Regulation 21 CFR 177.1520 and is suitable for food packaging applications		
Suggested Applications:	• Woven Industrial Fabric and Bags, Woven Carpet Backing, Woven Bags, Woven Geotextile Fabrics, Rope and Cordage		

1) Tests performed using compression-molded specimens.
(2) Tests performed using injection-molded specimens.
(3) The nominal properties reported herein are typical of the product but do not reflect normal testing variance and therefore should not be used for specification purposes.

March 1999

Phillips Sumika Polypropylene Company

Material Safety Data Sheet

MARLEX® POLYPROPYLENES (All Grades)

August 29, 1997

PHILLIPS SUMIKA POLYPROPYLENE COMPANY
2625 Bay Area Blvd., Suite 500
Houston, Texas 77058

PHONE NUMBERS
Emergency: (918) 661-8118
Technical Information: (918) 661-3072
For Additional MSDSs: (281) 244-3116
Product Information: (800) 231-1212

A. Product Identification

Synonyms: Plastic
Chemical Name: Propylene Polymers and Copolymers plus Additives
Chemical Family: Olefin Polymers and Copolymers plus Additives
Chemical Formula: Mixture
CAS Reg. No.: Mixture-See Section B for ingredient CAS Reg. No.
Product No.: Marlex Series

Product and/or Components Entered on EPA's TSCA Inventory: Yes

This product is in U.S. commerce, and is listed in the Toxic Substances Control Act (TSCA) Inventory of Chemicals; hence, it may be subject to applicable TSCA provisions and restrictions.

B. Components

This product, as shipped by Phillips Sumika Polypropylene Company, does not meet the definition of a hazardous material as given in 29 CFR Part 1910.1200 (OSHA). Information on this form is furnished as a customer service.

Ingredients	CAS Number	% By Wt.	OSHA PEL*	ACGIH TLV*
Polypropylene	9003-07-0	50-99	NE	NE
or				
Propylene Ethylene Copolymer	9010-79-1	50-99	NE	NE
also may contain:				
Polyethylene	9002-88-4	0-49	NE	NE
Ethylene Butene Copolymer	25087-34-7	0-49	NE	NE
Ethylene-Hexene-1 Copolymer	25213-02-9	0-49	NE	NE
Ethylene-Octene-1 Copolymer	26221-73-8	0-49	NE	NE
Additives	Various	0-4	NE	NE

* Also see Section F, Other Health Effects

C. Personal Protection Information

Ventilation: Use adequate ventilation to control concentration below recommended exposure limits. During molding and extruding processes, local exhaust may be needed to control off gases.

Respiratory Protection: Not generally required unless needed to prevent respiratory irritation from dust or off gases. If necessary during molding and extruding processes, use NIOSH/MSHA approved air purifying respirator equipped with an organic vapor cartridge and face mask. If concentrations of dust are high, use NIOSH/MSHA approved single-use dust respirator.

Eye Protection: Not generally required. Use chemical goggles if needed to prevent irritation from dust or off gases.

Skin Protection: No special garments required. Use heat resistant gloves when handling hot or molten material. When cleaning thermal decomposition off gas condensate from equipment, use full-body, long-sleeved garments to prevent skin contact.

NOTE: Personal protection information shown in Section C is based upon general information as to normal uses and conditions. Where special or unusual uses or conditions exist, it is suggested that the expert assistance of an industrial hygienist or other qualified professional be sought.

D. Handling and Storage Precautions

Wear protective equipment and/or garments described in Section C if exposure conditions warrant. Avoid breathing vapors, mists, fumes or dust. Wash thoroughly after handling. Launder contaminated clothing before reuse.

Store in a closed container. Store in a well-ventilated area. Moving pellets may generate static electric charge. Bond and ground during transfer.

Process only with adequate ventilation. Avoid breathing vapors from thermal processing off gases. Avoid eye or skin contact with thermal processing off gases. Thermal decomposition processing off gas condensate may form on surrounding equipment.

E. Reactivity Data

Stability: Stable
Conditions to Avoid: Not Applicable
Incompatibility (Materials to Avoid): Oxidants

Hazardous Polymerization: Will Not Occur
Conditions to Avoid: Not Applicable
Hazardous Decomposition Products: Carbon oxides and various hydrocarbon gases. Also, see Section F.

F. Health Hazard Data

Recommended Exposure Limits:

Control as Particulate Not Otherwise Classified (PNOC) or Regulated:

	OSHA PEL	ACGIH TLV
Respirable Fraction	5 mg/m3	3 mg/m3
Total Dust	15 mg/m3	10 mg/m3

Acute Effects of Overexposure:

Eye: Dust may cause mechanical irritation. Processing off gas vapors may cause irritation.

Skin: Essentially non-irritating.

Inhalation: Dust may produce mechanical irritation to the mucous membranes of the nose, throat and upper respiratory tract. Processing off gas vapors may cause irritation to the mucous membranes of the upper respiratory tract.

Ingestion: Essentially non-toxic and inert.

Subchronic and Chronic Effects of Overexposure:

Subchronic animal feeding studies have demonstrated no adverse effects with diets containing 5% or less polymer.

Other Health Effects:

Long term exposure to high dust concentrations may cause non-debilitating lung changes.

Thermal decomposition studies on polypropylene indicate that aldehydes (formaldehyde, acrolein, acetaldehyde, propionaldehyde, butyraldehyde, benzaldehyde); ketones (acetone, methyl ethyl ketone) and organic acids (formic acid, acetic acid) may be released during processing. These substances may be irritating to the mucous membranes of the eyes, nose, mouth, throat and lungs. Irritant effects should be transitory and can be eliminated with adequate ventilation.

Formaldehyde, which may be produced during thermal processing, is covered by the Formaldehyde Standard, 29 CFR 1910.1048.

Exposure to carbon monoxide, a combustion product of polypropylene, can result in carboxyhemoglobinemia. Carboxyhemoglobinemia is frequently misdiagnosed as flu.

Chronic exposure to carbon monoxide causes fatigue, poor memory, loss of sensation in fingers, visual disturbances and insomnia.

Subpopulations sensitive to the inhalation of carbon monoxide exist. Carbon monoxide displaces oxygen in the bloodstream and therefore, can adversely affect people with pre-existing heart disease, pregnant women and smokers.

Molten polymer may cause severe thermal burns. The interior of molten masses may remain hot for some time because of low thermal conductivity of the polymer. Use care when disposing of or handling such masses.

Health Hazard Categories:

	Animal	Human		Animal	Human
Known Carcinogen	___	___	Toxic	___	___
Suspect Carcinogen	___	___	Corrosive	___	___
Mutagen	___	___	Irritant	___	___
Teratogen	___	___	Target Organ Toxin	___	___
Allergic Sensitizer	___	___	Specify - No known applicable		

Highly Toxic ___ ___ information.

First Aid and Emergency Procedures:

NOTE: For thermal burns, cool quickly with water and seek immediate medical attention. Do not peel off solidified material.

Eye: Flush eyes with running water for at least fifteen minutes. If irritation or adverse symptoms develop, seek medical attention.

Skin: Wash skin with soap and water for at least fifteen minutes. If irritation or adverse symptoms develop, seek medical attention.

Inhalation: Remove from exposure. If breathing is difficult or irritation develops, seek medical attention.

Ingestion: Give two glasses of water and induce vomiting, only if subject is conscious. Seek medical attention.

G. Physical Data

Appearance:	Opaque, translucent waxy pellets or fluff.
Odor:	Mild
Boiling Point:	Not Applicable
Vapor Pressure:	Not Applicable
Vapor Density (Air = 1):	Not Applicable
Solubility in Water:	Negligible
Specific Gravity (H2O = 1):	Density is 0.88-0.92 g/cm3
Percent Volatile by Volume:	Negligible
Evaporation Rate (Butyl Acetate=1):	Not Applicable
Viscosity:	Not Applicable

H. Fire and Explosion Data

Flash Point (Method Used):	650F (343C) (ASTM D1929)
Flammable Limits (% by Volume in Air):	LEL - Not Applicable UEL - Not Applicable
Fire Extinguishing Media:	Dry chemical, foam or carbon dioxide (CO2)
Special Fire Fighting Procedures:	Evacuate area of all unnecessary personnel. Wear appropriate safety equipment for fire conditions including NIOSH/MSHA self-contained breathing apparatus (SCBA) and other protective equipment and/or garments as described in Section C if exposure conditions warrant. Use water fog or spray to cool exposed equipment and containers.
Fire and Explosion Hazards:	Carbon oxides and various hydrocarbons may be released when burned.

I. Spill, Leak and Disposal Procedures

Precautions Required if Material is Released or Spilled:
Wear protective equipment and/or garments described in Section C if exposure conditions warrant. If concentrations of product dust in air is high, eliminate all poss
ible ignition sources. Control dusts by wetting down with water spray. Spilled pellets may create slipping hazard. Sweep or vacuum up spill and place in drums for recovery or disposal. Keep out of water sources and sewers.

Waste Disposal (Insure Conformity with all Applicable Disposal Regulations):
Recover for reuse, recycle, incinerate for energy or place in a waste management facility.

J. DOT Transportation

Shipping Name: Not Applicable
Hazard Class: Not Applicable
ID Number: Not Applicable
Packing Group: Not Applicable
Marking: Not Applicable
Label: Not Applicable
Placard: Not Applicable
Hazardous Substance/RQ: Not Applicable
Shipping Description: Not Applicable
Packaging References: Not Applicable

K. RCRA Classification - Unadulterated Produc

Prior to disposal, consult your environmental contact to determine if the TCLP (Toxicity Characteristic Leaching Procedure, EPA Test Method 1311) is required. Reference 40 CFR Part 261.

L. Protection Required for Work on Contaminat

Contact immediate supervisor for specific instructions before work is initiated. Wear protective equipment and/or garments described in Section C if exposure conditions warrant.

M. Hazard Classification

___ This product meets the following hazard definition(s) as defined by the Occupational Safety and Health Hazard Communication Standard (29 CFR Section 1910.1200):

___ Combustible Liquid
___ Compressed Gas
___ Flammable Gas
___ Flammable Liquid
___ Flammable Solid
___ Flammable Aerosol
___ Explosive
___ Health Hazard (Section F)
___ Organic Peroxide
___ Oxidizer
___ Pyrophoric
___ Unstable
___ Water Reactive

_X_ Based on information presently available, this product does not meet any of the hazard definitions of 29 CFR Section 1910.1200.

N. Additional Comments

SARA 313

As of the preparation date, this product did not contain a chemical or chemicals subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

NFPA 704 Hazard Codes - - - - - - - - Signals

Health : 0	Least - 0
Flammability: 1	Slight - 1
Reactivity : 0	Moderate - 2
Special Haz.: -	High - 3
	Extreme - 4