K020882

JUL 2 6 2002

5. 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter Address:	Surgical Specialties Corporation 100 Dennis Drive Reading, PA 19606
Telephone: Contact Person:	610 404 1000, ext. 2231 Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	March 15, 2002

Name of Device:	Sharpoint® UltraPlug™ Extended Wear Plug
Common / Usual Classification Name:	Punctum Plug

Predicate Devices:	**Indications for use Predicate Devices:** Surgidev Silicone Punctum Plug, US IOL Inc, Occu-Flo Punctum Plug, Eagle Vision Temporary Intracanalicular Collagen Insert Surgical Specialties Corporations (formerly Look, Inc.) Temporary Intracanalicular Collagen Implant. **Material Predicate Device:** Surgical Specialties Corporation's PCL Monofilament Synthetic Absorbable Suture Material.

Device Description	UltraPlug Extended Wear Punctum Plug are intended for temporary use with patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by blockage of the canaliculus. The Sharpoint UltraPlug Extended Wear Plug is made from absorbable suture material. The plugs are available in two lengths 1.6mm and 2.0mm, and in three diameters: 0.2mm, 0.3mm and 0.4mm.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Indications of Use:	UltraPlug™ Extended Wear Punctum Plugs may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases such as corneal ulcers, conjunctivitis, pterygium, blepharitis, keratitis, red lid erosion, filamentary kerstitis and other external eye diseases. When indicated, UltraPlug Extended Wear Punctum Plug may be used after ocular surgery to prevent complications due to dry eye and to enhance the retention of ocular medications. Patients experiencing dry eye related contact lens problems also may be aided by UltraPlug Extended Wear Punctum Plugs.
Technological Characteristics	UltraPlug™ Extended Wear Punctum Plug is made of PCL Absorbable Synthetic Suture material. ε-Caprolactone-L-Lactide Copolymer. This material has been approved for ophthalmic usage in SSC's 510(k) K003015. The material has been well characterized through absorption studies and biocompatibility studies. The product is similar to the predicate device, Eagle Vision Temporary Intracanalicular Collagen insert, in that they are both made from absorbable materials.
Punctum Plugs:	PCL Plugs are a synthetic absorbable suture material, which will dissolve in 180 days (reference 510(k) K003015 data). Collagen Plugs provide temporary lacrimal occlusion by reducing tears drainage through Partial blockage of the horizontal canaliculus. Collagen Plugs dissolve in 7 to 10 days. Silicone Plugs are permanent in that they do not dissolve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Specialties Corporation
c/o Ms. Elizabeth Lazaro
Regulatory Affairs Specialist
100 Dennis Drive
Reading, PA 19606 3776

JUL 2 6 2002

Re: K020882
Trade Name: Sharpoint® UltraPlug™ Extended Wear [Punctal] Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: June 25, 2002
Received: June 26, 2002

Dear Ms. Lazaro:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

4. FDA INDICATIONS FOR USE FORM

510(k) Number (if known): K020882

Device Name: Sharpoint® UltraPlug™ Extended Wear Plug

Indications for Use:

Sharpoint® UltraPlug™ Extended Wear Plug may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases. When indicated, UltraPlug™ Extended Wear Plugs may be used after ocular surgery to prevent complications due to dry eye and to enhance the retention of ocular medications. Patients experiencing dry eye related contact lens problems also may be aided by UltraPlug™ Extended Wear Plugs.

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

CONCURRENCE OF CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)

Donna R. Vachon

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K020882