Tab 5

Premarket Notification [510(k)] Summary

NOV 8 2012

Submission Date:	November 1, 2011
Trade Name:	DCS Lacrimal Stent
Common Name:	Lacrimal Stent and Intubation Sets
Classification /Name:	Unclassified
Device Code:	OKS
Manufacturer's Name: Address:	DCS Surgical, Inc. 1110 Linden Ave. Boulder, CO 80304
Corresponding Official: Title: Address: Telephone:	Harry Ross, MD CEO / President 1110 Linden Ave. Boulder, CO. 80304 303-929-9909

Predicate Devices:

Gunther-Weiss	Pre-Amendment Jones Tubes	
FCI Ophthalmics	K061404	Mono-Crawford Nasolacrimal Intubation Device
Eagle Vision, Inc.	K030353	Lacrimal Stents and Intubation Sets

Indication for Use:

The DCS Lacrimal Stent is intended for use during repair of the lacrimal system for intubation and bypass to canalicular pathologies.

Device Description:

The DCS Lacrimal Stent is a sterile, single-use lacrimal stent. The DCS Lacrimal Stent is a hollow flexible silicone lacrimal stent designed to be positioned distally in the paranasal cavities and proximally at the medial fornix conjuntival reflection. It is

composed of a medical grade silicone tube with an internal diameter of 1.0 mm and with a total length of 15.5 mm.

Comparison Table of the DCS Lacrimal Stent to the Predicates

Manufacturer (Device) / Attributes	Gunther Weiss *(Jones Tubes)*	**DCS Surgical (*Lacrimal Stent*)**	FCI Ophthalmics K061404 Mono-Crawford Naso-Lacrimal Intubation Device *(Monokas)*	Eagle Vision K030353 Lacrimal Stents and Intubation Sets *(MonoStents)*
Indication for Use	Intended for use during repair of the lacrimal system for intubation and bypass to canalicular pathologies.		Lacrimal Stents are intended for use in lacrimal system reconstruction. This includes, but is not limited to, treatment of epiphora; canalicular pathologies such as stenosis; obstruction or laceration; and conditions requiring dacryocystorhinostomy.	
Device Class; Product Code	21 CFR 886.4350; Class I; HNL	Unclassified; Product Code OKS		
Material	Pyrex Glass	Medical Grade Silicone Tubing		
Stent Outer Diameter	2.0 mm	1.5 mm to 2.25 mm	0.64 mm	0.9 mm
Punctum Collar Diameter	3.0 to 5.5 mm range of diameters	2. 5 mm by 6.0 mm	3.0 mm and 4.0 mm	1.6 mm by 2.1 mm
Stent Length	9 mm to 40 mm range of lengths	15.5 mm	50 mm	.50 mm
Packaging and Sterility	User prepared for steam or gas sterilization	Tyvek Pouch; Radiation Sterilized for Single Use Only		

Device dimensions are suitable for the intended uses. Any differences in technology are in regards to the manner by the devices are designed, with the narrower / longer 510(k) predicates for intra-ductal intubation and the wider / shorter Jones Tubes and DCS Lacrimal Stents for extra-ductal intubation. These differences do not raise any new questions of safety or effectiveness.

Performance Testing

The performance of the DCS Lacrimal Stent was verified by bench and cadaver testing to have adequate tensile strength and internal flow profile for intubation of the nasal punctum and lacrimal anatomy to facilitate the drainage of tear fluid from the eye.

Biocompatibility

The medical grade silicone material used in the DCS Lacrimal Stent was successfully tested for biocompatibility and is suitable for the intended use as a prolonged contact

duration device, externally communicating with tissue, bone, dentin, as described in ISO 10993. The biocompatibility is substantially equivalent to the 510(k) predicate devices and there are no new types of safety questions.

Sterilization

The Device is labeled sterile, for single-use only. The packaging and contents are radiation sterilized by a validated process to a Sterility Assurance Level (SAL) of 10^{-6} per ANSI/AAMI/ISO 11137-2 for radiation sterilization of health care products.

Substantial Equivalence

The DCS Lacrimal Stent was evaluated in accordance with 21 CFR 807.87(d - g) to verify substantial equivalence to the predicate devices. The applicable predicates are identified in the comparison table provided in this summary. The attributes and technological comparisons to the predicates support the substantial equivalence of the DCS Lacrimal Stent for its intended use. Combined with the product performance and biocompatibility testing, the DCS Lacrimal Stent is substantially equivalent in function, technology and intended use to the commercially available predicate devices. Any differences between the DCS Lacrimal Stent and the predicates do not raise any new types of safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DCS Surgical, Inc.
% Harry Ross, M.D.
CEO/President
1110 Linden Avenue
Boulder, CO 80304

NOV 8 2012

Re: K113316
Trade/Device Name: DCS Lacrimal Stent
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: OKS
Dated: October 22, 2012
Received: October 24, 2012

Dear Dr. Ross:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113316

Device Name: DCS Lacrimal Stent

Indications for Use:

The DCS Lacrimal Stent is intended for use during repair of the lacrimal system for intubation and bypass to canalicular pathologies.

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

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

510(k) Number K113316