

Section 15**Summary of Safety and Effectiveness**

The 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

- | | |
|--------------------------|--|
| a. Submitter: | STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016
(626) 303-7902 |
| b. Contact Person: | Helene Lamielle |
| c. Date Summary Prepared | May 14, 2004 |

2. Name of device, including trade name and classification name:

- | | |
|----------------------------|---------------------------|
| a. Trade/Proprietary Name: | Collamer 3 Piece Injector |
| b. Classification Name: | Intraocular Lens Guide |

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed.

- | | |
|------------------|-----------------------------|
| a. Company: | STAAR Surgical Company |
| b. Device: | MS1-P Elastic Lens Injector |
| c. 510(K): | K861085 |
| d. Date Cleared: | 5/28/1986 |

4. A description of the device that is the subject of the 510(K) including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Collamer 3 Piece Injector is made of titanium alloy designed for inserting intraocular lenses into the human eye following cataract extraction. The Collamer 3 Piece Injector materials and mechanical behavior are similar to those used with the predicate device.

5. Statement of intended use:

The Collamer 3 Piece Injector is an intraocular lens guide used to fold and insert STAAR Surgical's 3 Piece Collamer intraocular lenses for surgical placement in the human eye.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Comparative Technological Characteristics

CHARACTERISTICS	Collamer 3 Piece Injector	MS1-P Elastic Lens Injector
Intended Use	For Surgical placement of an intraocular lens in the human eye	Same
Material	Titanium, 6-Aluminum, 4-Venadium, and PEEK (polyetheretherketone)	Titanium
Sterilization	Provided non-sterile, may be steam sterilized	Provided non-sterile; may be steam sterilized
Mode of Operation	Intraocular lenses are folded and placed inside a lens cartridge made from polypropylene. The lens is then pushed down via a plunger and plunger rod and expelled from the lens cartridge into the human eye.	Same
Single Use or Re-useable	Re-usable	Same

7. Brief summary of non-clinical tests and results:

The Collamer 3 Piece Injector has been designed and tested in accordance with applicable safety standards. In addition, the Collamer 3 Piece Injector was found to perform equivalently to the predicate device, the MS1-P Elastic Lens Injector with respect to mechanical performance and mechanical behavior.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2004

STAAR Surgical Company
c/o Helene Lamielle, M.D.
1911 Walker Ave.
Monrovia, CA 91016

Re: K032412

Trade/Device Name: Collamer 3 Piece Injector
Regulation Number: 21 CFR 886.4300
Regulation Name: Ophthalmic lens guide
Regulatory Class: Class I
Product Code: KYB
Dated: May 14, 2004
Received: May 17, 2004

Dear Dr. Lamielle:

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) 594-4613. 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,

A handwritten signature in cursive script that reads "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

Enclosure

Indications for Use

510(k) Number (if known): K032412

Device Name: STAAR Surgical Collamer 3 Piece Injector

Indications For Use:

The Collamer 3 Piece IOL Injector, is an intraocular lens guide used to fold and insert STAAR Surgical 3 Piece Collamer Intraocular Lenses into the capsular bag or ciliary sulcus following cataract extraction.

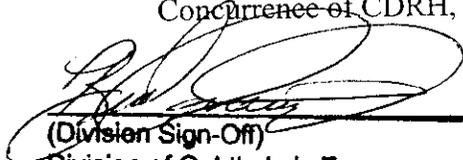
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 Ear,
Nose and Throat Devices

510(k) Number K032412