K980696

SEP 11 1998

PREMARKET NOTIFICATION [510(k)] SUMMARY FOR FOAM TIP™ INJECTOR SYSTEM K980696

Trade name: Foam Tip™ Injector System
Common name: Foldable Intraocular Lens Injector System
Classification name: Intraocular Lens Guide per 21 CFR, Section 886.4300
Ophthalmic sponge per 21 CFR, Section 886.4790

Submitted by: STAAR Surgical Company
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Contact Person: Steven L. Ziémba
Vice-President, Regulatory Affairs
Phone: (626) 303 - 7902, ext. 2308

Date Summary Prepared: 8/12/98

Legally Marketed Predicate Device: MicroSTAAR™ Injector System (reusable and disposable) manufactured by STAAR Surgical Company.

Intended Use of the Device: The Foam Tip™ Injector is a device used to fold and insert STAAR Surgical UV-ELASTIC™ silicone lenses for surgical placement in the human eye.

Device Description: STAAR Surgical Company's Foam Tip™ Injector is used to fold and insert STAAR Surgical UV-ELASTIC™ silicone intraocular lenses for surgical placement into the human eye. The new Foam Tip™ Injector utilizes the same design principles (i.e. a plunger pushing or threaded mechanism) to push the IOL through a cartridge for injection into the eye as the existing MicroSTAAR™ injectors. The new injector system differs from the MicroSTAAR™ injector in that it contains a disposable Foam Tip™ plunger insert which may be attached to the sterilized injector body prior to lens loading. This attachable Foam Tip™ plunger insert is encapsulated inside a holder that protects the sponge from damage. The holder acts to guide the plunger as it slides into the injector body and performs as a wrench to remove the plunger from the injector once the lens has been implanted. Once the sponge portion of the foam plunger insert is hydrated, it

enables the surgeon to have greater control in ejecting the lens properly through the cartridge and into the eye. Like the existing MicroSTAAR™ injectors, the new Foam Tip™ Injector body is provided sterile and can be resterilized for multiple use. The new Foam Tip™ plunger insert is also provided sterile but is intended for single use only.

Nonclinical Performance Testing:

Functional Testing

A total of 40 functional ejection tests were conducted on STAAR Surgical single-piece UV-ELASTIC™ silicone lenses. A matrix was used to define the injector/lens/cartridge combinations, with a minimum of ten lenses per injector/cartridge combination. Two types of injectors were tested with the Foam Tip™ plunger inserts, the plunger design and the threaded design. (The plunger type injector requires that the user push or pull on the knob cap to move the plunger. The threaded plunger requires that the user turn the threaded cap clockwise or counterclockwise to move the plunger.)

Acceptance Criteria for the Lens Injection Test for Foam Tip™ Injectors included:

- No lens tears (an indication that the lens was properly loaded)
- All post-ejected lenses meet STAAR's minimum resolution efficiency requirements
- No haptic damage
- Gross particulate evaluation

All 40 functional test lens ejections passed minimum resolution testing. There was no evidence of haptic damage or lens tears. Particulates were noted in both the Test and Control samples. None appeared to be greater than 10 microns in size.

Accelerated Aging Studies

The following tests were performed :

- Dust Drum - Microbial Challenge
- Dye Penetration tests:
  - Seal Strength
  - Burst Test
  - Cytotoxicity per USP 23 <87>
  - FTIR
  - Sponge degradation Analysis
  - Package integrity

The results of the accelerated aging tests, specifically the Microbial Challenge Dust Drum Test, Dye Penetration and Burst tests indicate that both sample groups (baseline versus six month) provided an acceptable microbial barrier and kept product sterile within. Slight variations in seal strength were within an acceptable range and did not appear to have compromised the sterile barriers or the integrity of the product.

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Cytotoxicity tests showed that the material was non-toxic and along with the FTIR demonstrated that E-Beam sterilization was an acceptable method of sterilization.

LAL testing was also performed which indicated that bacterial endotoxins were not above FDA limits, thereby providing acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Steven Ziémba
Vice-President, Regulatory Affairs
STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016

Re: K980696
Trade Name: Foam Tip™ Injector System
Regulatory Class: I
Product Code: MSS
Dated: August 12, 1998
Received: August 14, 1998

Dear Mr. Ziémba:

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 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). 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 requirements, 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) 594-4613. 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" (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,

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

Enclosure

510(k) Number: K980696

Device Name: Foam Tip™ Injector

Indications For Use:

The Foam Tip™ Injector is a device used to fold and insert STAAR Surgical UV-ELASTIC™ single-piece silicone lenses for surgical placement in the human eye.

There are no marketing claims for this device at this time.

(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)

Claudine L. Kraweczyk for DRL
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980696