K983129

DEC 4 1998

PREMARKET NOTIFICATION [510(K)] SUMMARY FOR THE DISPOSABLE MicroSTAAR™ INJECTOR SYSTEM

Trade/Proprietary Name: Disposable MicroSTAAR™ Injector (Model MSI-P1)
Common/Usual Name: Disposable IOL Injector
Classification Name: Foldable Intraocular Lens Injector

Submitted by: STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016
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Contact Person: Steven L. Ziemba
Vice-President, Regulatory Affairs
Phone: (626) 303-7902 ext. 2308

Date Summary Prepared: September 4, 1998

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

Intended Use of the Device:: The Disposable MicroSTAAR™ Injector (Model MSI-P1) is a device used to fold and insert STAAR Surgical UV-ELASTIC™ silicone lenses for surgical placement in the human eye.

Device Description: The Disposable MicroSTAAR™ Injector (Model MSI-P1) is used to fold and insert STAAR Surgical UV-ELASTIC™ silicone intraocular lenses for surgical placement in the human eye. Like other MicroSTAAR injectors it provides a sterile tubular pathway through a surgical incision, over the iris and into either the ciliary sulcus or the capsular bag of the eye. The Disposable MicroSTAAR™ Injector (Model MSI-P1) is made from plastic and the inner dimensions of the delivery pathway, as well as the outer dimensions of the portion that contacts the eye tissues are identical to STAAR Surgical Company's currently marketed injection systems. The Disposable MicroSTAAR™ Injector (Model MSI-P1) is provided sterile and is designed for single use.

Nonclinical Performance Testing:

Functional Testing: A functional validation was performed using thirty sterile Disposable MicroSTAAR™ Injectors (Model MSI-P1) to eject thirty UV-ELASTIC™ lenses. The acceptance criteria for the lens ejection test included the following:

- No optic zone lens tears for properly loaded lenses.
- All post-ejected lenses to meet a minimum resolution ≥ 3.6.

The lens ejection test results showed no lens tears in addition to meeting the minimum resolution requirements.

Accelerated Aging Study: The following tests were performed on baseline (zero time) and one year accelerated samples as part of the validation:

- Microbial Challenge - Dust Drum
- Dye Penetration
- Peel Strength
- Burst

The Microbial Challenge - Dust Drum test reports indicate all samples and negative controls to be "NEGATIVE" and the positive controls to be "POSITIVE" which are acceptable results.

The Dye Penetration test reports indicate all samples as "Pass".

The Peel Strength tests compared the mean maximum seal strength for the baseline and one-year accelerated age samples using the T-test and F-test analysis. The results indicate that the sample means and variances are statistically similar.

The Burst tests compared the baseline and one-year accelerated age samples using the T-test and F-test analysis. The results of the analysis of the large pouch indicate that the sample means and variances are statistically similar. No statistical analysis was required for the small pouch as there were no failures.

Overall, the non-clinical test results demonstrate that the sterilized Disposable MicroSTAAR™ Injector (Model MSI-P1) successfully ejects lenses and the packaging maintains adequate integrity to ensure product sterility for a period of one year.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

Steven L. Ziemba
Vice President, Regulatory Affairs
STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016

Re: K983129
Trade Name: Disposable MicroSTAAR™ Injector (Model MSI-P1)
Regulatory Class: I
Product Code: 86 KYB
Dated: September 4, 1998
Received: September 8, 1998

Dear Mr. Ziemba:

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

INDICATIONS STATEMENT

510(k) Number: k983129

Device Name: Disposable MicroSTAAR™ Injector

Indications For Use: The Disposable MicroSTAAR™ Injector is a device used to fold and insert STAAR Surgical Company UV-ELASTIC™ single-piece silicone lenses for surgical placement in the human eye.

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)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983129