DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN 8 1992

Mr. Henry Shapiro
President
H. S. International Co., Inc.
5040 Commercial Circle
Unit A
Concord, CA 94520

Re: K920987
Trade Name: Disposable Microscissors
Regulatory Product Class: I
Product Codes: 86 HNF
Generic Name: Disposable Intraocular Scissors
Dated: February 22, 1992
Received: March 2, 1992

Dear Mr. Shapiro:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this product.

The final classification regulation for your device was published in the Federal Register on September 14, 1988, Vol. 53, No. 178, pp. 35602-35607. Copies of this regulation is enclosed for your information. Beginning with the effective date of these regulations, manufacturers of Disposable Intraocular Scissors are exempt from the premarket notification requirements of the Act. We suggest that you review these regulations since they may grant other exemptions from certain general controls of the Act. Your device's product codes, generic names and regulatory class are shown above. If you are required to list your device with the Food and Drug Administration, please use these product codes.

In the future, new but substantially equivalent Disposable Intraocular Scissors Devices may be marketed without sending a premarket notification submission to the Food and Drug Administration.

If you have any questions regarding this letter, please contact Denis L. McCarthy at (301) 427-1209 or the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Nancy C. Brogdon for

Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1996

Mr. Henry Shapiro
H.S. International Co., Inc.
5040 Commercial Circle, Unit A
Concord, CA 94520

Re: K955771
Trade Name: Intraocular Microscissors, Reusable
Product Code(s): 86 HNF
Classification Regulation: 886.4350
Regulatory Class: I
Dated: December 19, 1995
Received: December 21, 1995

Dear Mr. Shapiro:

We have reviewed your premarket notification submission and have found this medical device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device.

The final classification regulation for your device was published in the Federal Register on September 2, 1987, Vol. 52, page 33346 or December 7, 1994, Vol. 59, page 63005. Beginning with the effective dates of these regulations, manufacturers of devices falling within the above classification regulation are exempt from the premarket notification requirements of the Act if they comply with the classification criteria. We suggest that you review these regulations since they may grant other exemptions from certain general controls of the Act. Your device's product code, classification regulation and regulatory class are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall with the above classification regulation and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration.