SEP 25 1998

K983123

Section 7

SEP 25 1998

510(k) SUMMARY

SUBMITTERS INFORMATION

Name and Address

Precision Optics Corporation
22 E. Broadway
Gardner, MA 01440
Telephone 978.630.1800

Contact Person

James A. Reilly, Quality Assurance Manager

Date of Summary

26 June 1998

DEVICE NAME

Proprietary Name:	ENT Endoscope - Sinuscope
Common Name:	Sinuscope
Classification Name:	Sinuscope

PREDICATE DEVICE IDENTIFICATION

Predicate devices referenced include Precision Optics Corporation's endoscopes (Laparoscope and Arthroscope).

SUBSTANTIAL EQUIVALENCE

Precision Optics Corporation's ENT Endoscope – Sinuscope is substantially equivalent to cited predicate Endoscope devices since the basic features, design, and primary functions are the same. Any minor differences in design and dimensions between the Precision Optics Corporation's ENT Endoscope – Sinuscope and the predicate devices raise no new issues of safety and effectiveness as these differences have no effect on the safety, performance and function of the ENT Endoscopes.

This device will be identical with respect to external materials, construction, and fundamental operational principles to Precision Optics Corporation's current line of cleared Laparoscopes (K914084) and Arthroscopes (K945684) except for variations of tube diameter and insertion length.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

James A. Reilly
Manager, Quality Assurance
Precision Optics Corporation
22 East Broadway
Gardner, MA 01240

Re: K983123
POC ENT Endoscope - Sinuscope
Dated: June 30, 1998
Received: July 1, 1998
Regulatory class: II
21 CFR 874.4760/Procode: 77 EOB

Dear Mr. Reilly:

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 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Intended Use:

Precision Optics Corporation's ENT Endoscopes - Sinuscopes are indicated for use to examine or treat the nasal cavity and nasal pharynx by providing illumination and visualization of these regions.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983123

Prescription Use ✓
(Per 21 CFR 801.109)