

Ka 84556

**510(k) Summary - Summary of Safety and Effectiveness Information**

**Submitter's Name & Address:** Schölly Fiberoptic GmbH  
 Robert-Bosch-Strasse 1-3  
 D-79211 Denzlingen

**Contact Person:** Carsten Schlenker

**Telephone & Fax:** Tel.: 00 49 - 76 66 - 9 08 - 2 05  
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**Date Summary Prepared:** October 30, 1998

**Device Name:** Device trade Name - SciCan Classic  
 Common Name - Video Camera System and Accessories  
 Classification Name - Unit, Operative Dental

**Predicate Device:** Welch Allyn Reveal Intraoral Camera System  
 [ 510(k) number K981937 ]

**Device Description, Intended Use & Effectiveness:**

The purpose of the SciCan Classic and accessories is to provide video images of the mouth and oral structures, dental cavities, dental pulps, dental canal morphology. It is used to perform various diagnostic procedures, to provide educational information to patients as well as to other clinical personnel and to provide documentation for patient records and for insurance companies.

SciCan Classic also is used for inspection of retentions and as reliable diagnosis of border gaps when dealing with inlays. Additionally it acts as an effective caries detector during the examination of areas of the mouth which are normally difficult to approach. Further indications for use are extra-oral imaging of the whole face and of the mouth, outline imaging of the quadrants and macroscopic images of the dental enamel.

**Technological Characteristics:**

Comparison feature	SciCan Classic	Welch Allyn Reveal (K981937)
General		
design	modular design due handpiece system with interchangeable optics	modular design due handpiece system with interchangeable optics (lenses)
power consumption	150 Watt	144 Watt
Camera Typ	Video camera system	Video camera system
Video System	NTSC / PAL	PAL
Camera chip	CCD 1/2"	CCD 1/4"
Illumination	fiber optic illumination provided by an integrated light source	fiber optic illumination provided by an integrated light source
light control	CCD, automatic exposure control	CCD, automatic exposure control
handpiece	removable and interchangeable probe options	removable and interchangeable lens (probe) options
probes	90° probes, 0° probe	90° probes, 0° probe
standards met	IEC 601-1, IEC 601-1-2 (DIN EN 60601-1-2), IEC-601-2-18	IEC 601, EN 60601-1-2, AS3200.1.0

**Summary of Safety:**

The SciCan Classic was designed to provide safety to the patient as well as the user and assisting personnel. The device complies with IEC 601-1, IEC 601-1-2, and IEC 601-2-18.

**Summary of Effectiveness:**

The SciCan Classic is effective for its intended use of providing video images for the above described purposes and procedures.

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last change /by:	-	department:	R&D
revision:	0	page	13



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 9 1999

Mr. Carsten Schlenker  
Regulatory Affairs Manager  
Scholly Fiberoptic GmbH  
Robert-Bosch-Strasse 1-3  
D-79211 Denzlingen

Re: K984556  
Trade Name: Scican Classic  
Regulatory Class: I  
Product Code: EIA  
Dated: November 29, 1998  
Received: December 23, 1998

Dear Mr. Schlenker:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

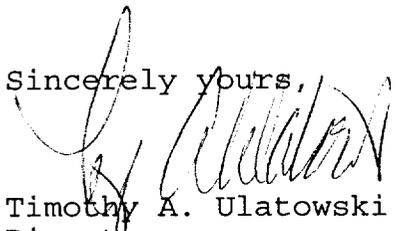
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (21CFR 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K984556

Device Name: SciCan Classic

Indications For Use:

The SciCan Classic and accessories are indicated for use when video images are desired to provide visual information during dental examinations and procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Ruvor

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K984556

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use