

AUG 24 1998

K981937

"510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn Inc.
4619 Jordan Road, Box 187
Skaneateles Falls, New York 13153-0187

Contact Person & Telephone: Kathy Lowther
(315) 685-2897

Date Summary Prepared: May 27, 1998

Device Name: Classification Name - Unit, Operative Dental
Common/Usual Name - Intraoral Camera
Proprietary Name - Welch Allyn Reveal Intraoral Camera System

Predicate Device: UltraCam Intraoral Camera System (510(k) number K933671)

Device Description, intended Use & Effectiveness:

The purpose of the Welch Allyn Reveal Intraoral Camera System is to provide video images of the mouth and oral structures. Video images aid in patient education and insurance documentation. The intended use of the Welch Allyn Reveal Intraoral Camera System is to provide video images during dental examinations and procedures. The Welch Allyn Reveal Intraoral Camera System is effective in its intended use.

Technological Characteristics:

See Attachment "A" for a comparison of the features and specifications of the Welch Allyn Reveal Intraoral Camera System and the predicate device.

Summary of Safety:

The Welch Allyn Reveal Intraoral Camera System was designed to provide safety to the patient as well as the user. The system complies with IEC 601-1, EN 60601-1-2, and UL 2601.

Summary of Effectiveness:

The Welch Allyn Reveal Intraoral Camera System is effective for its intended use of providing video images during dental examinations and procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1998

Ms. Kathy Lowther
Quality Engineer
Welch Allyn, Incorporated
4619 Jordan Road, Box 187
Skaneateles Falls, New York 13153-0187

Re: K981937
Trade Name: Welch Allyn Reveal Intraoral Camera System
Regulatory Class: I
Product Code: EIA
Dated: May 29, 1998
Received: June 2, 1998

Dear Ms. Lowther:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Page 2 - Ms. Lowther

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" (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,



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): _____

Device Name: Welch Allyn Reveal Intraoral Camera System

Indications For Use:

The Welch Allyn Reveal Intraoral Camera System is indicated for use during dental examinations and procedures when a video image is desired.

(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

(Optional Format 1-2-96)

Susan R. ...
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number k981937