

2/11/99

K984215

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

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, N.Y. 13153-0220

Contact Person & Telephone: Colin Wolff
(315) 685-2525

Date Summary Prepared: November 19, 1998

Device Name: Classification Name - Picture Archiving and Communication System
Common/Usual Name - Dictation System with PACS
Proprietary Name - Welch Allyn Front-Line Doc

Predicate Device: model Image Vault (ref. 510(k) #K974102)

Device Description, Intended Use & Effectiveness:

Front-line Doc™ is a medical imaging and documentation system. It consists of a hand-held portable instrument and software applications bundled to enhance office transcription and documentation. Software applications can be utilized on a PC to perform the transcription, review, and management tracking and reporting processes.

The Welch Allyn model #77000 Front-Line Doc™ system is intended for dictation and also enhances medical records by allowing physicians to add images to their dictated patient notes. The device is intended to be used by trained personnel within a medical or school environment.

The effectiveness of the Front-Line Doc system is the same as current dictation systems and PACS already on the market.

Technological Characteristics:

See attachment "A" for a comparison of the Front-Line Doc to the predicate device.

Safety:

Numerous safety areas were investigated and reviewed to ensure that the Welch Allyn Front-Line Doc System is as safe, or safer than existing similar devices already in commercial distribution. The device under review is considered very safe for both practitioner and patient. It is non-contact for the patient. The procedure and technique are low risk. The specific safety areas considered are as follows:

Toxicity - The device is not intended to contact any patient. It is made of materials that are skin compatible.

Electrical - has agency approval based on standards from UL 544.

Light - Light output levels are consistent with output from safe use journal

- Explosion - Highly unlikely; manufactured of non-explosive materials. The batteries are protected from an electrical short condition.
- Surface - All surfaces have been evaluated for practitioner contact.
- Temperature
- Fire Hazard - Probability extremely low; this system uses a low voltage halogen lamp, which draws a maximum of 5 watts power. The video and audio portions are also low voltage.
- Mechanical - All contact surfaces have been blended and
(Sharp Edges) rounded. No injury will result from sharp edges.
- Software - Risk Analysis, FMEA, and Verf.& Valid. performed for software.

Summary of Effectiveness:

The determination of device effectiveness was coordinated in the following manner:

The Welch Allyn Front-Line Doc development team conducted on-site evaluations of the device with practicing physicians in an effort to determine if the device met all of the practitioner's needs. The evaluating practitioners were also users of either an existing dictaton, or other model dictation and imaging devices (all have the same intended use). The results of the evaluations indicated that the Welch Allyn Front-Line Doc System serves the needs of the documentation procedure in an equivalent or better manner of effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1999

Colin Wolff
Certified Quality Engineer
Welch Allyn, Inc.
4341 State Street Rd.
Skaneateles Falls, NY 13153-0220

Re: K984215
Welch Allyn Front-Line Doc
Dated: November 20, 1998
Received: November 24, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Wolff:

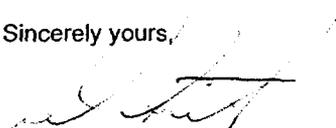
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 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,



Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984215

Device Name: Welch Allyn Front-Line Doc

Indications For Use:

The Welch Allyn model #77000 Front-Line Doc™ system is intended for dictation and documentation. It also enhances medical records by allowing physicians to add images to their dictated patient notes. The device is intended to be used by trained personnel within a medical or school environment.

(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

David G. Seymour
(Division Sign-Off)

(Optional Format 1-2-96)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K984215