

EB-1830T3 Video Bronchoscope Special 510k  
Exhibit B

1023376

OCT 16 2002

510(k) Summary  
EB-1830T3, Video Bronchoscope

**Submitter Information:** Pentax Precision Instrument Corporation (PPIC)  
30 Ramland Road  
Orangeburg, NY, 10962  
Tel: (845)-365-0700

**Name of Device:**

Trade Name:	EB-1830T3, Video Bronchoscope
Classification Name:	EOQ, Bronchoscope

**Predicated Device(s) Information:**

Model, Description	Manufacturer	PMN#
VB-1830, Video Bronchoscope	PPIC	K934920

**Intended Use:**

The EB-1830T3, Video Bronchoscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, the Pulmonary Tract. The Pulmonary Tract includes, but is not restricted to, the organs; tissues; and subsystems: Nasal Passage, Pharynx, Larynx, Trachea, and bronchial Tree (including access beyond the stem). The instrument is introduced per oral or per nasal when indications consistent with the requirement for the procedure are observed in adult and pediatric patient populations.

**Device Description:**

The EB-1830T3, Video Bronchoscope, must be used with a Video Processor (a software controlled device). The endoscope has a flexible insertion tube, a control body, and umbilicus. The umbilicus provides connection to the video processor and connections for suction. The umbilicus provides connection to the video processor. The control body includes controls for up/down angulation, suction, and an accessory inlet port. The device contains light carrying bundles, to illuminate the body cavity, and a charge couple device (CCD) to collect image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced (the instrument is supplied with two biopsy forceps). The video processor contains an illumination system that is focused at the connected video endoscope lightguide prong. The endoscope light carrying bundles present the video processor illumination to the body cavity and the CCD collects image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

**Comparison To Predicated Device(s):**

The submission for substantial equivalence included comparisons to the predicated device, proposed labeling, summary of design control activities, and summary of Quality Assurance and Manufacturing Controls. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Prepared by: Paul Silva  
Control Number: PS-726

Signature:



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Date: 10-02-2002

Revision: a



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 16 2002

Pentax Precision Instrument Corporation  
c/o Paul Silva  
Regulatory Affairs Coordinator  
30 Ramland Road  
Orangeburg, NY 10962

Re: K023376  
Trade/Device Name: EB-1830T3, Video Bronchoscope  
Regulation Number: 21 CFR 874.4680  
Regulation Name: Bronchoscope (flexible or rigid) and accessories  
Regulatory Class: Class II  
Product Code: EOQ  
Dated: October 4, 2002  
Received: October 8, 2002

Dear Mr. Silva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

EB-1830T3 Video Bronchoscope Special 510k  
Exhibit C

Indications for Use

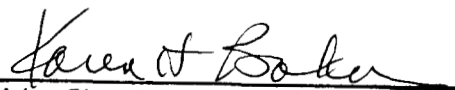
510(k) Number (if known): K023376 Page 1 of 1  
Device Name: EB-1830T3, Video Bronchoscope

**Endoscope Intended Use Statement:**

The EB-1830T3, Video Bronchoscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, the Pulmonary Tract. The Pulmonary Tract includes, but is not restricted to, the organs; tissues; and subsystems: Nasal Passage, Pharynx, Larynx, Trachea, and bronchial Tree (including access beyond the stem). The instrument is introduced per oral or per nasal when indications consistent with the requirement for the procedure are observed in adult and pediatric patient populations.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K023376