OCT 8 1998

K982484

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI Spinal Endoscopic System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Jon Caparotta
   Electro-Biology, Inc.
   6 Upper Pond Road
   Parsippany, NJ 07054

   Contact Person: Jonas Wilf
   Telephone: (973) 299-9022 X2208

   Date prepared: July 16, 1998

2. **Proprietary Name:** EBI VueCath™ Spinal Endoscopic System
   Common Name: Arthroscope
   Classification Name: Arthroscope and Accessories (888.1100)

3. **Predicate or legally marketed* devices that are substantially equivalent:**

   - EBI Spinal Endoscopic System – Electro-Biology, Inc.
   - Myelotec Myeloscope System - Myelotec Inc.

4. **Description of the device:** The EBI VueCath™ Endoscopic Spinal System is an arthroscope consisting of several components and different accessories for viewing the lumbar and sacral spinal anatomy. This system includes a fiberscope, disposable catheter, and various accessories. The fiberscope is designed to connect to any compatible commercially available endoscopic video imaging system by using a camera coupler and light cord adaptors.

5. **Intended Use:** The EBI VueCath Spinal Endoscopic System is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease utilizing a caudal approach via the sacral hiatus.

6. **Materials:** The catheter is the patient contacting portion of the system. It is manufactured from medical grade polyurethane. The outer jacket of the fiberscope is made out of polyimide.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI VueCath™ Spinal Endoscopic System and another spinal arthroscope currently on the market. It is substantially equivalent to the virtually identical Myelotec Myeloscope System device in design, materials and intended use. Also, bench testing demonstrates that the device meets its functional requirements.

*Any statements made in conjunction with this submission regarding a determination of substantial equivalence to any other product or to "legally marketed" products are intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and are not intended to be relevant to or interpreted as an admission or any other type of evidence in either patent infringement litigation or any other context. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1998

Mr. Jonas Wilf
Regulatory Affairs Specialist
Electro-Biology, Inc.
6 Upper Pond Rd.
Parsippany, New Jersey 07054

Re: K982484
Trade Name: EBI VueCath™ Spinal Endoscopic System
Regulatory Class: II
Product Code: HRX
Dated: July 16, 1998
Received: July 17, 1998

Dear Mr. Wilf:

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 requirement, 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) 594-4659. 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

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The EBI VueCath™ Spinal Endoscopic System is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease utilizing a caudal approach via the sacral hiatus.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982484