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K062841

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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**Date:** August 28, 2009

**Submitter:**

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**Product:**

<u>Trade Name:</u>	Spinal Foraminoscope
<u>Classification:</u>	Class II
<u>Common Name:</u>	Foraminoscope
<u>Classification Name:</u>	Arthroscope

**Predicate Devices:**

- Yeung Endoscopic Spine System, Richard Wolf Medical Instruments Corp., K973405
- Spine Scope, Model 2180, Clarus Medical, LLC., K011454
- Pollux Arthroscopes, Pollux Endoscopy, Inc., K953484

**Device Description:** The Spinal Foraminoscope for lumbar access is an optical and fiberoptic-based rigid endoscope provided with a 2.8 or 3.7 mm working channel and two 1.5-mm irrigation channels and allowing insertion of 2.8-mm or 3.5-mm hand-held instruments.

The Spinal Foraminoscope for cervical access is a fiberoptic-based rigid endoscope which shares the same design. It is provided with a 2.2-mm working and irrigation channel, has a 3.6-mm outer diameter and allows insertion of 2.0-mm hand-held instruments.

The Spinal Foraminoscope may be attached to standard fiberoptic light sources and Storz, Olympus, Wolf and ACM cameras and video adapters.

**Intended Use:** The Spinal Foraminoscope is intended for endoscopic visualization of the lumbar and cervical spine.

**Performance Data:** Testing was performed to support substantial equivalence to the predicate device. The Spinal Foraminoscope met all specified design and performance requirements.

**Sterilization** The Spinal Foraminoscope is offered non-sterile for autoclave steam sterilization.

**Conclusion:** Based upon the product technical information provided, intended use and performance information provided in this premarket notification, as well as similarity to legally marketed devices, Blazejewski MEDI-TECH GmbH considers the Spinal Foraminoscope to be substantially equivalent to the current legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

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Blazejewski Medi-Tech GmbH  
% Business Support International  
Ms. Angelika Scherp  
Regulatory Affairs Consultant  
Amstel 320-I  
Amsterdam 1017AP  
Netherlands

Re: K082841  
Trade/Device Name: Spinal Foraminoscope  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: Class II  
Product Code: HRX  
Dated: August 28, 2009  
Received: August 31, 2009

Dear Ms. Scherp:

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 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); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Spinal Foraminoscope**

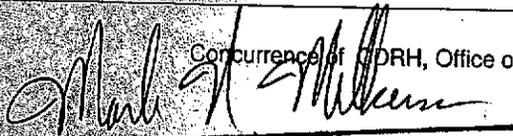
**Indications for Use:** The Spinal Foraminoscope for lumbar access is indicated for endoscopic visualization in the lumbar region. The Spinal Foraminoscope for cervical access is indicated for visual inspection of the cervical spinal nerve roots and surrounding tissue.

Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 807 Subpart C)

(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 Surgical, Orthopedic,  
and Restorative Devices

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