SEP 2 6 2002

K020457

# 510(k) Summary of Safety and Effectiveness

In Accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: AXIAMED, Inc.
   Address: 5200 Willson Road
   Suite 150
   Edina, MN 55424

   Phone: 952 836-2660
   Fax: 952 836-2661

   Contact: W. Allen Putnam
   Date of Summary Preparation: July 12, 2002

2. Name of Device: AXIAMED Trans-Sacral Spinal Access Device
   Generic Name: Rigid Endoscope and Instrument Set

3. Predicate Devices:

   Surgical Dynamics, Inc., 30K Working Channel Scope and instrument kit for Discectomy

   Argus Medical Company Laparoscopic Discectomy Instrument System

   The Nucleotome System and Probe Kits.

   Surgical dynamics Discography System

   Sofamor Danek USA, Inc., Micro Endo Instruments

4. Device Description:

   The AXIAMED Trans-Sacral Spinal Access Device is for minimally invasive access to the anterior lower spine and consists of the following components:

   Blunt Trocar with Trocar Guide Stylet
   Threaded Guide
   Dilator Sheath, Small
   Dilator Sheath, Large
   Threaded Guide Sheath, 3mm
   Threaded Guide Sheath, 4mm
   Drill Bit, 3 mm
   Drill Bit, 4mm
   Delivery Cannula with blunt stylet

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2002

Mr. W. Allen Putnam
AXIAMED, Inc.
5200 Wilson Road, Suite 150
Edina, Minnesota 55424

Re: K020457
Trade Name: AXIAMED Trans-Sacral Spinal Access Device
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: July 12, 2002
Received: July 15, 2002

Dear Mr. Putnam:

We have reviewed your Section 510(k) premarket 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) 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) 594-4659. 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" (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,

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

Enclosure

K020457

INDICATION FOR USE

The intended use of the AXIAMED Trans-Sacral Spinal Access Device is for minimally invasive access to the anterior portion of the lower spine for the purpose of assisting in the treatment of decompression of the lumbar disc or the performance of lumbar discectomy.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020457