

MAR 18 1998

**510(k) Summary**  
**INCLUSIVE® Endoscopic System**  
**K963642**  
**January 16, 1998**

- I. **Company:** Sofamor Danek  
1800 Pyramid Place  
Memphis, TN 38132  
(901) 396-3133
- II. **Product Name:** INCLUSIVE® Endoscopic System
- III. This submission describes an endoscopic system and ancillary equipment. The endoscope consists of light transmitting optical fibers and an image transmitting fiber bundle contained within the scope.
- IV. The INCLUSIVE Endoscope is indicated for aiding in the search and removal of nucleus material and for visualization of lumbar herniated discs. It is intended to be used percutaneously in the lumbar spine. The endoscope is also intended for visualizing the tissues of the brain and for use in the knee, shoulder, wrist and the temporomandibular joint (TMJ).
- V. The INCLUSIVE Endoscope Device was claimed to be substantially equivalent to various commercially available arthroscopic and endoscopic systems. Information pertaining to these systems was provided in the submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

Mr. Richard W. Treharne  
Vice President, Research and Regulatory Affairs  
Sofamor Danek  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K963642  
Trade Name: Inclusive Endoscopic System  
Regulatory Class: II  
Product Code: GWG  
Dated: January 16, 1998  
Received: January 16, 1998

Dear Mr. Treharne:

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 (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 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.

Page 2 - Mr. Treharne

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) 594-4595. 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,

*for Stephen Rhoads*

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

January 16, 1998

510(k) Number (if known): K963642

Device Name: INCLUSIVE® Endoscope

Indications for Use:

The INCLUSIVE® Endoscope is indicated for aiding in the search and removal of nucleus material and for viewing herniated disc material in the lumbar spine via a percutaneous surgical approach. The endoscope is also indicated for visualizing the tissues of the brain and for use in the knee, shoulder, wrist and the temporomandibular joint (TMJ).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Stephen Rhoads*

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K963642

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)