K972450

510(k) Summary
FlexTip™ Grasper

NOV 21 1997

1. SUBMITTER NAME AND ADDRESS

Endius Incorporated
23 West Bacon Street
Plainville, MA 02762
Telephone: (508) 643-0983
Telefax: (508) 695-2501

Contact: Thomas W. Davison, Ph.D.

2. DEVICE NAME

Proprietary Name:	FlexTip™ Grasper
Common/Usual Name:	Forceps
Classification Name:	Ear, nose and throat manual surgical instrument; manual arthroscopic instrument

3. PREDICATE DEVICES

- Endo-bend™ Grasper (Aust & Taylor Medical Corp.)
- Precisor Disposable Forceps and Graspers Reusable Graspers (Smith & Nephew Dyonics, Inc.)
- AMD™ System (Smith & Nephew Dyonics, Inc.).

4. INTENDED USE

The FlexTip™ Grasper is a manual instrument intended for use in tissue grasping, dissecting and cutting in surgical or endoscopic sinus procedures and arthroscopic orthopedic and microdiscectomy surgery.

5. DEVICE DESCRIPTION

The Endius Incorporated FlexTip™ Grasper is composed of:

- a tissue engaging tip of either a through cut or biting design
- a series of nested high density polycarbonate vertebra joints which allow articulation of the grasper tip
- a shaft section which connects the flexible end to the handle
- a radius control sheath used to control the radius of curvature of the flexible tip
- a pistol grip handle containing the control mechanism for the grasper tip.

6. TECHNOLOGICAL CHARACTERISTICS

The Endius Incorporated FlexTip™ Grasper and the substantially equivalent devices are all used for grasping, holding, manipulating or removal of tissue during surgical procedures. Tissue grasping is accomplished using a pivoting jaw configuration.

The Smith & Nephew Dyonics, Inc. devices all have rigid shafts with jaws either straight or at a specified angle. The proposed FlexTip™ Grasper and the Endo-bend™ Grasper have a flexible shaft due to the presence of a series of nested vertebrae joints, which allow adjustable shaft angulation. The Endo-bend™ Grasper can curve upward to 180°. The FlexTip™ Grasper can articulate 110° either above or below the plane of the shaft. A high density polyethylene radius control sheath slides over the stainless steel vertebrae to control the radius of curvature of the tip. The articulation feature of the FlexTip™ Grasper eliminates the need for numerous instruments with different tip angles.

The jaws of the Aust & Taylor Medical Corp. Endo-bend™ Grasper are of a biting forceps design. The proposed device and the Smith & Nephew Dyonics, Inc. disposable and reusable graspers and forceps have biting forcep and through cut jaw configurations in a variety of sizes.

The Smith & Nephew Dyonics, Inc. predicate devices use a scissor handle to open and close the jaws of the instrument. The Aust & Taylor device uses a trigger handle for jaw operation which is equivalent in design to that used in the proposed FlexTip™ Grasper.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynthia J. M. Nolte, Ph.D.
Associate Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K972450
FlexTip™ Grasper
Dated: October 14, 1997
Received: October 15, 1997
Regulatory class: II
21 CFR 874.4760/Procode: 77 EOB
21 CFR 888.1100/Procode: 87 HRX

NOV 21 1997

Dear Dr. Nolte:

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) 594-4613. 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" (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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972450

Device Name: FlexTip™ Grasper

Indications For Use:

The FlexTip™ Grasper is a manual instrument intended for use in tissue grasping, dissecting and cutting in surgical or endoscopic sinus procedures and arthroscopic orthopedic and microdiscectomy surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972450

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)