

OCT 21 1999

Page 10

K992898

**SECTION 6**

**510(k) SUMMARY**

**Submitter's Name:** Bright Medical Instruments

**Submitter's Address:** 799 N.E. 71<sup>st</sup> Street  
Boca Raton, Florida 33467

**Contact Person:** Robert E. Simonson

**Telephone:** 877-527-4448

**Facsimile:** 561-998-8224

**Date Prepared:** July 30, 1999

**Device Trade Name:** Dilation Retractor System

**Device Common Name:** Surgical Retractor

**Classification Name:** Self-Retaining Retractor for Neurosurgery

**Predicate Device:** Sofamor Danek MicroEndoscopic  
Discectomy Retractor System

**Device Description:** Series of dilators, tubular retractors of various lengths and guide wire for use in providing access to the spine for minimally invasive discectomy procedures.

**Intended Use:** To provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the retractor, down to the lamina, with its attachment to a flexible arm to provide a self locking method of access to the spinal site through which a microscope and surgical instruments can be manipulated.

Technological Characteristics  
and Comparison to Predicate

The Bright Medical **Dilation Retractor System** is manufactured from equivalent materials, with similar dimensions, to achieve the same surgical objectives as the predicate MED MicroEndoscopic Discectomy System.

Performance Data:

When used as designed, the **Dilation Retractor System** functions in as safe and effective a manner as the predicate device.

Conclusion:

The Bright Medical **Dilation Retractor System** is safe and effective and is substantially equivalent to the predicate device.



OCT 21 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert E. Simonson  
President  
Bright Medical Instruments  
799 North East 71<sup>st</sup> Street  
Boca Raton, Florida 33487

Re: K992898  
Trade Name: Bright Medical Dilation Retractor System  
Regulatory Class: II  
Product Code: GZT  
Dated: July 29, 1999  
Received: August 27, 1999

Dear Mr. Simonson:

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.

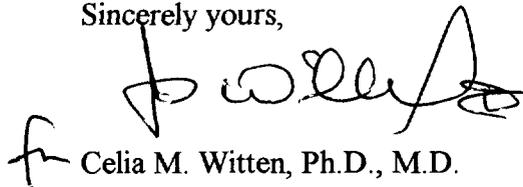
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Robert E. Simonson

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

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

K992898

**SECTION 5**

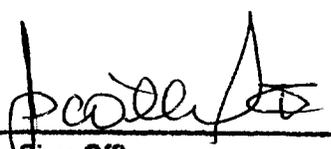
**INDICATIONS FOR USE**

**Bright Medical Dilation Retractor System**

Provide a self-locking device to hold the edges of a wound open for neurosurgical procedures.

---

Prescription Use  or Over the Counter



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K992898