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KLS L.P.

## 510(K) SUMMARY K060097

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| **Submitter:** | KLS-Martin, L.P.<br>11239-1 St. Johns Industrial Parkway South<br>Jacksonville, FL 32246<br>Phone: 904-641-7746<br>Fax: 904-641-7378 |
| **Contact Person:** | Jennifer Damato<br>Director RA/QA |
| **Date of Summary:** | 10 January 2006 |
| **Device Name:** | Grossman Self-Retaining Low Profile Brain Retractor |
| **Trade Name:** | Grossman Self-Retaining Low Profile Brain Retractor |
| **Common Name:** | Retractor, Self-Retaining |
| **Classification Name and Number:** | Retractor, Self-Retaining, For Neurosurgery (CFR 882.4800) |
| **Regulatory Class:** | II |
| **Predicate Devices:** | Budde®-Halo Retractor (K830332)<br><br>Tew Cranial/Spinal Retractor Model A 1090 (K960807) |
| **Device Description:** | The Grossman Self-Retaining Low Profile Brain Retractor is designed to retract soft tissue during neurosurgical procedures. |
| **Device Description:** | The Grossman Self-Retaining Low Profile Brain Retractor is a flexible multi segmented device. The device consists of a flexible multi segmented arm, interchangeable blades, and a clamping fixture to anchor the retractor arm in place. The flexible arm and the clamp fixture are constructed of Stainless Steel and Anodized Aluminum components. The retractor blades are constructed from Stainless Steel. |

**Technological Characteristics:**

**Similarities to Predicate**

The Grossman Self-Retaining Low Profile Brain Retractor is similar in application to the Budde®-Halo Retractor (Halo Retractor Arm) (K830332) and the Tew Cranial/Spinal Retractor Model A1090 (Flexible Micro-Retractor Arm) (K960807).

**Differences to Predicate**

The Grossman Self-Retaining Low Profile Brain Retractor is a stand alone device that is independently mounted and does not rely on a complete system to be utilized.

**Substantial Equivalence:**

The Grossman Self-Retaining Low Profile Brain Retractor is substantially equivalent in design and application to the Budde®-Halo Retractor (Halo Retractor Arm) (K830332) and the Tew Cranial/Spinal Retractor Model A1090 (Flexible Micro-Retractor Arm) (K960807).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

KLS-Martin, L.P.
c/o Ms. Jennifer Damato
Director
Regulatory Affairs and Quality Assurance
11239 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K060097
Trade/Device Name: Grossman Self-Retaining Low Profile Brain Retractor
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GZT
Dated: January 10, 2006
Received: January 13, 2006

Dear Ms. Damato:

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.

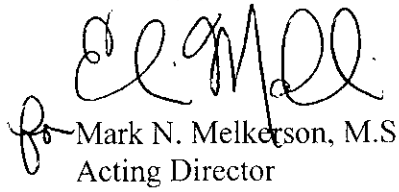
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K060097

Device Name: Grossman Self-Retaining Low Profile Brain Retractor

Indications For Use:

The Grossman Self-Retaining Low Profile Brain Retractor is designed to retract soft tissue during neurosurgical procedures.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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)

[signature]

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

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