APR 2 7 2001

K003940

1 of 2

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	AESCULAP® INC. APRIL 13, 2001

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Trade Name: **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation

Common Name(s): Spinal retractor

Classification Name(s): Spinal retractor, self-retaining retractor for neurosurgery

Establishment Name & Registration Number:

Name: Aesculap® Inc.
Number: 2916714

Classification(s):

§ 882.4800 Self retaining retractor for neurosurgery.

(a) Identification. A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.

(b) Classification. Class II (performance standards).

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Neurosurgery Devices Panel
Product Code(s): HRX, GZT

Applicant Name & Address:

AESCULAP® Inc.
944 Maroon Blvd.
Allentown, PA 18109
650.876.7000 voice - 650.876.0266 fax

Company Contact:

Ms. Joyce Thomas
Aesculap® Inc.
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Allentown, PA 18109
650.876.7000 voice - 650.876.0266 fax

Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Labeling:

The **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation discussed in this summary is made in Germany by AESCULAP® AG & CO. KG. The system will be marketed exclusively to healthcare facilities and physicians.

Surgical Technique. The surgical approach used with the **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation is similar to other spinal retractor systems and instruments.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician only.

Preamendments Device (legally marketed comparison device):

AESCULAP® Inc. believes that the **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation is substantially equivalent to the following spinal retractors marketed by Surgical Dynamics, Inc. and Brigfht Medical Instruments.

- **Surgical Dymanics Spinal Retractor - K002008, Surgical Dynamics, Inc.**
- **Heyer- Shulte Corporation, K780706,** Lumbar Nerve Root Shield
- **Dilation Retractor System - K992898, Bright Medical Instruments, Inc.**

To facilitate comparison of the **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation to the systems identified above, a basic feature comparison table is located at the end of the document.

Summary Basis for Equivalence and Comparison Table:

- The devices have the same intended use and/or indications for use.
- The devices are made of comparable instrument grade materials.
- The devices have similar function, surgical approach, instruments and features.

The use of ISO & QSR based process controls and the similarities of the references comparison devices establish that the **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation is substantially equivalent to available legally marketed spinal retractors. It is believed that the anticipated clinical performance of the **miaspas® miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation is equivalent to the referenced systems.

Summary Comparison Table:

FEATURE	**miaspas®** miniTTA Anterior Micro Surgical Transthoracic Approach Instrumentation	Surgical Dynamics Spinal retractor	Bright Medical Dilation retractor System	SE?
Indications for Use:	The device is intended for use as a specialized manual surgical instrument. It is reusable and is intended to provide access to the anterior thoracic and lumbar spinal column during minimally invasive and endoscopic surgical procedures. Provides a self-locking type surgical retraction system with inflatable tissue protectors.	Hollow rigid instrument for use in spine surgery for viewing and instrument access to the vertebral space. Retracts tissue during open and endoscopic procedures.	Dilators, tubular retractors & guide wires used to provide minimally invasive surgical access to the spine. Positioned down to the surface of the spine using self-locking flexible arm.	YES
Components:	Tray, retractor, counter retractor, lung retractor, rib retractor Sm. & Lg., diaphragm retractor Sm., Med., Lg., Lung retractor w/ inflatable cuff Sm., Med., Lg., handle for retractor blades, forceps for retractor blade & drape.	3 sizes	5 dilators, 3 tubular retractors, 1 guidewire, flexible attachment arm.	YES
Sterilization:	Steam autoclave	Same	Same	YES
				YES
Materials:	Titanium alloy	Stainless steel	Stainless Steel	YES
				YES
Manufacturer	Aesculap	Surgical Dynamics, Inc.	Bright Medical, Inc.	YES
Surgical Approach:	Transthroacic	Lateral/transthoracic	Lateral/transthoracic	YES
Product Code:	GZT, HRX	GZT, HRX	GZT	YES
K - Number:	Pending	K002008	K992898	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Aesculap, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory lane
Suite C-100
Pleasant Hill, California 94523

Re: K003740
Trade/Device Name: miaspas® miniTTA Anterior Micro Surgical Transthoracic Approach Instrumentation
Regulation Number: 888.1100, 882.4800
Regulatory Class: II
Product Code: HRX, GZT
Dated: February 7, 2001
Received: March 12, 2001

Dear Mr. Schlerf:

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 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). 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 requirements, 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) 594-4659. 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 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

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

510(k) Number : K003740

Device Name(s): **miaspas®** **miniTTA** Anterior Micro Surgical Transthoracic Approach Instrumentation

Indications for Use:

Self-retaining retractor for neurosurgery & Spinal retractor

The device is intended for use as a specialized manual surgical instrument. It is reusable and is intended to provide access to the anterior thoracic and lumbar spinal column during minimally invasive and endoscopic surgical procedures. Provides a self-locking type surgical retraction system with inflatable tissue protectors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhran

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

510(k) Number K003740

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)