

K960807

II SUMMARY AND CERTIFICATION

Summary of Safety and Effectiveness TEW Cranial/Spinal Retractor™

Pursuant to Section 513(I) of the Federal Food, Drug and Cosmetics Act.

1. General Information:

Classification Name: Self-retaining retractor for neurosurgery

Common/Usual Name: Self-retaining Retractor

Proprietary Name: TEW Cranial/Spinal Retractor™

Applicant's Name and Address: F. William Sweet, Regulatory Affairs Manager
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3924 Virginia Avenue.
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2. Name of predicate device(s):

Karlín Crank Frame Spinal Retractor Set
Apfelbaum Cerebellar Retractor
Budde® Halo Retractor - for blades, micro-retractors and flex arms

3. Classification:

Self-retaining retractor for neurosurgery are Class II (21CFR 882.4800).

4. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description:

Intended Use: The TEW Cranial/Spinal Retractor (A-1090) is designed for posterior fossa or intraspinal microsurgery where retraction is required.

The TEW Cranial/Spinal Retractor is a combination of a frame retractor body for skin or muscle retraction and flexible micro-retractor arms for delicate neural tissue retraction.

Device Description: TEW Cranial/Spinal Retractor™ is made from titanium and the blades, micro-retractors and flexarm assemblies are made from stainless steel. It has two movable arms, which operate independently by rotating a worm on a worm gear thus allowing an acme threaded shaft to translate through the worm gear (Patent pending). The

II SUMMARY AND CERTIFICATION - Continued

5. Intended Use and Device Description: - Continued

mechanism of the TEW Retractor is self locking due to the worm/worm gear design. A hex wrench is used to drive the system.

TEW Retractor blades can be pre-attached to the arms outside of the wound and a formed locking edge on the blades prevent them from falling off. The blades can also be pre-positioned and once retraction has been initiated, blades will remain in a fixed position..

TEW Retractor micro-retraction is accomplished by unrestricted placement of the flexarm assemblies along the entire length of the retractor arms. There is no limit to the number of flexarms that can be used.

Options:

A-1055	Tew Micro-Retractors
A-1057	Curved Blades
A-1071	Serrated TEW Micro Retractors
A-1074	Tapered Retractor Blade Set
A-1076	Hooked TEW Micro Retractors
4-38-A-1011	9" Flex Arm
4-38-A-1012	12" Flex Arm
4-38-A-1140	Halo Mini Vise Assembly

6. Summary of Substantial Equivalence:

Indications: The TEW Cranial/Spinal Retractor (A-1090) is designed for posterior fossa or intraspinal microsurgery where retraction is required.

Design: KARLIN Retractor crank frame has one movable arm, operated by rotating a pinion gear on a gear rack with a latch lock on the rack teeth. A square drive wrench is used to drive the system.

TEW Retractor has two movable arms, operating independently by rotating a worm on a worm gear allowing an acme threaded shaft to translate through the worm gear. The mechanism of the TEW Retractor is self locking due to the worm/worm gear design. A hex wrench is used to drive the system.

KARLIN Retractor blades are pre-positioned in the wound. The blades have no locking device to keep them from falling off the arms if blade attachment is performed outside of the wound.

TEW Retractor blades can be pre-attached to the arms outside of the wound and a formed locking edge on the blades prevent them from falling off. The blades can also be pre-positioned and once force is applied to them they will snap into place.

II SUMMARY AND CERTIFICATION - Continued

6. Summary of Substantial Equivalence - Continued

Blade configuration between the KARLIN and TEW is the same for the only blade that KARLIN offers with differences of width and height. TEW also has blades with points for anchoring to bone and another for soft tissue use.

TEW Retractor micro-retraction is accomplished by unrestricted placement of the flexarm assemblies along the entire length of the retractor arms. There is no limit to the number of flexarms that can be used. KARLIN Retractor has a self-retaining attachment to either retractor arm from which a single slide holder can be positioned along the arm length. Suction retractors are mounted in the slide holder and placed accordingly. The KARLIN attachment allows for two such retractors.

APFELBAUM Retractor, self-retaining retractor with 4x4 prongs. It has a pawl and gear rack lock system, similar to a rack and pinion gear lock, and two hexagonal posts fixed to each arm for flexarm attachment. Two flexarms can be used with the unit.

APFELBAUM Retractor uses the 4x4 prong for retaining tissue instead of separate blades capable of moving on a retractor arm system such as KARLIN or TEW. Three blades are available with the APFELBAUM unit for micro-retraction, one set being a left and right hand.

Materials: KARLIN Retractor, blades and self-retaining attachment is made from stainless steel.

TEW Retractor is titanium and the blades are stainless steel. TEW self-retaining flexarm assemblies are made from stainless steel

APFELBAUM Retractor and blades are made from stainless steel and blades are malleable for soft tissue use.

Manufacturing: The manufacturing processes (milling, turning, wire cutting and forming) used in the TEW Cranial/Spinal Retractor™ are the same as those used in the predicate devices (Karlín Crank Frame Spinal Retractor and Apfelbaum Cerebellar Retractor).

Specifications: The specifications of the TEW Cranial/Spinal Retractor™ are the same as those of the predicate devices.

Conclusion: The indications, design, materials, manufacturing and specifications of the TEW Cranial/Spinal Retractor™ do not raise any new issues relating to safety and effectiveness.

OMI thus considers the TEW Cranial/Spinal Retractor™ to be equivalent to the predicate devices.