



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 16, 2015

Thompson Surgical Instruments, Inc.
Stephanie Myers, Product Manager
10170 East Cherry Bend Road,
Traverse City, MI 49684

Re: K151347
Trade/Device Name: MIS Spine Frame Instrument Case
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 15, 2015
Received: September 18, 2015

Dear Ms. Myers,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151347

Device Name
MIS Spine Frame Instrument Case

Indications for Use (Describe)

Thompson Surgical Instruments MIS Spine Frame Instrument Case is intended for use in healthcare facilities to store, transport, organize, and sterilize surgical instruments such as retractor blades, retractor frame components, lighting accessories, and blade or frame accessories between uses when used in combination with an FDA cleared sterilization wrap. Validated sterilization parameters include pre-vacuum steam and gravity.

CYCLE	CYCLE TEMP	EXPOSURE TIME	DRY TIME
Prevacuum	132°C (270°F)	4 Minutes	30 Minutes
Gravity	121°C (250°F)	30 Minutes	30 Minutes

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Submitter:
Thompson Surgical Instruments,
Inc.

Product:
MIS Spine Frame Instrument Case

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510(k) Summary

Submitter Name: Thompson Surgical Instruments, Inc.

Submitter Address: 10170 E Cherry Bend Rd
Traverse City, MI 49684

Contact Person: Stephanie Myers, Research & Development /Product Manager

Phone Number: 231-922-5170

Fax: 231-922-0174

Date Prepared: September 14, 2015

Device Trade Name: MIS Spine Frame Instrument Case

Classification Name: Sterilization Wrap Containers, Cassettes, and Accessories

Device Class: Class II

Classification Regulation: 21 CFR 880.6850

Product Code: KCT

Predicate Device: The instrument case described in this submission was compared and found to be substantially equivalent to the K3131170 Sonicision™ Sterilization Tray manufactured by Covidien. K3131170 was cleared August 28th, 2013.

Statement of Intended Use: Thompson Surgical Instruments MIS Spine Frame Instrument Case is intended for use in healthcare facilities to store, transport, organize, and sterilize surgical instruments such as retractor blades, retractor frame components, lighting accessories, and blade or frame accessories between uses when used in combination with an FDA cleared sterilization wrap. Validated sterilization parameters include pre-vacuum steam and gravity.

CYCLE	CYCLE TEMP	EXPOSURE TIME	DRY TIME
Prevacuum	132°C (270°F)	4 Minutes	30 Minutes
Gravity	121°C (250°F)	30 Minutes	30 Minutes

Device Description: Thompson Surgical Instruments “MIS Spine Frame Instrument Case,” model 50000MSF, is intended to hold surgical instruments such as retractor blades, retractor frame components, lighting accessories, and blade or frame accessories during storage, transportation, and sterilization, as indicated. It is composed of materials that can be reused with steam sterilization methods and DCG graphics may be used. It has a distribution of perforations on the outer surfaces and between case levels that allow for optimal steam penetration. Vent to volume is .110. It is reusable

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and provided to the customer in a non-sterile conditions. This case can be described as an accessory for the Thompson Retractor.

**Technological and
 Performance
 Characteristics:**

The MIS Spine Frame Instrument Case was found to be similar to the predicate. Three fundamental similarities are:

1. Basic design: Both the MIS Spine Frame Instrument Case and the predicate have a basic lid/base design with latches, handles, perforations, and contoured inserts or sections for containing items for sterilization, storage, and transport. General size, shape, weight, and materials are not identical but are similar.
2. Role in sterile barrier system: The MIS Spine Frame Instrument Case and the predicate must be enclosed with a qualified FDA cleared sterilization wrap to maintain sterility. Neither contains gaskets, valves, or filters.
3. Fundamental Technology: The MIS Spine Frame Instrument Case and the predicate allow the sterilant (steam) to penetrate and render its contents sterile by relying on surface perforations.

Primary differences are related to minor variances in size, shape, intended contents, surface perforations, and overall look. However, performance data demonstrate that the differences do not adversely affect safety and effectiveness. Please see further comparison below.

**Comparison to
 Predicate Device:**

	Proposed: MIS Spine Frame Instrument Case	Predicate: Sonicision™ Sterilization Tray K131170
<i>Intended Use:</i>	Thompson Surgical Instruments MIS Spine Frame Instrument Case is intended for use in healthcare facilities to store, transport, organize, and sterilize medical devices and other instrumentation between uses when used in combination with a FDA cleared sterilization wrap.	To encase and protect reusable batteries and generators of the Sonicision system during sterilization and storage. Compatible sterilization systems are indicated as follows: STERRAD® 100s, STERRAD® NX®, STERRAD® 100NX®, STERIS Amsco® V-PRO® 1, STERIS Amsco® V-PRO® 1 Plus, STERIS Amsco® V-PRO® maX
<i>Design Characteristics:</i>		
<i>-Composition:</i>	Base, lift out tray, and lid	Base and lid

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<i>-Intended content (max load):</i>	Medical devices/instruments weighing no less than 25lbs total including the weight of the MIS Spine Frame Instrument Case.	One Sonicision generator and one battery pack
<i>-Inserts:</i>	Yes	Yes
<i>-Handles:</i>	Yes	Yes
<i>-Latches:</i>	Yes	Yes
<i>-Reusable:</i>	Yes	Yes
Materials:		
<i>-Lid/base/lift out tray not including inserts:</i>	Aluminum	Polysulfone
<i>-Inserts:</i>	Silicone, Aluminum, Stainless Steel, Nylon	Silicone
<i>-Latch:</i>	Stainless steel	Polysulfone
Assembled Dimensions:	11" x 23.5"	5.9" X 8.1"
Weight containing max load:	25 lbs	1.58 lbs
Percent of surface perforations on lid, base, lift out tray:	Lid has 15.7%, lift out tray has 19.2%, and base has 13.6%	9.7%

**Non-Clinical
 Performance Studies:**

The MIS Spine Frame Instrument Case was evaluated in accordance with applicable clauses/criteria specified in AAMI 5T77:2006. Test evidence supporting sterilization efficacy, cleaning, and biocompatibility are provided in the submission. A brief discussion of tests used to support the conclusion of substantial equivalence with the predicate device is provided below.

Sterilization efficacy: The MIS Spine Frame Instrument Case and the predicate containing the maximum load were inoculated with biological indicators placed in areas of the trays deemed to be most difficult for sterilant (steam) to penetrate. Following inoculation, the trays were wrapped in FDA cleared sterilization wraps.

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They trays were then exposed to the sterilization cycles (Steam sterilization for the MIS Spine Frame Instrument Case and STERRAD or STERIS sterilization for the predicate). The results for both trays indicated that half cycles provided a six log reduction of the indicator organism.

Cleaning: The MIS Spine Frame Instrument Case was tested for cleanability. The results indicated a pass. Supporting evidence is included in the submission.

Biocompatibility: The MIS Spine Frame Instrument Case is considered non-cytotoxic as based on MEM elution test results. Supporting evidence is found in the submission.

**Clinical Performance
Studies:**

This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:

The MIS Spine Frame Instrument Case is substantially equivalent to the Sonicision™ Sterilization Tray, K131170. None of the differences between the MIS Spine Frame Instrument Case and the predicate change the intended use or raise new questions of safety or effectiveness.

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