510(k) SUMMARY K073551

MAY 21 2008

Smith & Nephew® Instrument Tray
Date Prepared: May 20, 2008

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Julie Acker RAC
Regulatory Affairs Specialist
T: 508-261-3618
F: 508-261-3620
Julie.acker@smith-nephew.com

C. Device Name

Trade Name:	Instrument Tray
Common Name:	Instrument Tray
Classification Name:	Sterilization Wrap Containers, Trays Cassettes and Other Accessories
Class:	Class 2
Product Code	KCT

D. Predicate Devices

The Smith & Nephew instrument tray is substantially equivalent in design, materials, and intended use to the following devices in commercial distribution: PolyVac Surgical Instrument Delivery System 510(k)# K012105 and Riley Medical, Inc. Meta-Pak Multipurpose Instrument Tray 510(k)# K993535

E. Description of Device

The Smith & Nephew instrument tray is designed to contain and protect reusable surgical instruments during transport, sterilization, and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

The instrument tray is a perforated stainless steel case with latchable lid and handle. The tray is fitted with Radel® organizing racks, silicone instrument holders and protective mats. The instrument tray is marked to facilitate organized instrument placement.

F. Intended Use

The Smith & Nephew instrument tray is intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The instrument tray is suitable for use in prevacuum steam and high temperature gravity steam sterilization methods.

The instrument tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Prevacuum Steam	132°C – 135°C (270°F-275°F)	4 minutes	30 minutes
High Temperature Gravity Steam	132°C (270°F)	10 minutes	70 minutes

Device model that is the subject of this pre-market notification:

REF	Description
72201731	Tray, ACUFEX® DIRECTOR ELITE® Drill Guide Systems

G. Comparison of Technological Characteristics

The Smith & Nephew instrument tray is substantially equivalent in design, materials and intended use to the predicate devices. The proposed instrument tray and predicate devices are used for storage, transport and sterilization of reusable surgical instruments between uses. Both the proposed and predicate devices are suitable for use in steam sterilization processes when used in conjunction with legally validated sterilization wrap and are not intended to maintain sterility on the own.

The Smith & Nephew instrument tray does not incorporate any new technological characteristics as compared to legally marketed devices. The Smith & Nephew instrument tray and the predicate devices are cases constructed of perforated metal with latchable lid, and utilize radel organizing racks, silicone instrument brackets and protective mats to secure encased instruments. There are no significant differences between the proposed and predicate devices.

Performance testing including sterilization efficacy testing, thermal profile studies and drying time studies demonstrate that the Smith & Nephew instrument tray conforms to AAMI ST77:2006 *Containment Devices for reusable medical device sterilization*.

H. Summary and Conclusions

The Smith & Nephew instrument tray has the same intended use, technological characteristics and performance characteristics as the legally marketed predicate devices. The product design is in conformance with recognized consensus standards and does not raise any new issues of safety and efficacy. We consider the Smith & Nephew Instrument Tray to be substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2008

Ms. Julie Acker
Regulatory Affairs
Smith & Nephew, Incorporated, Endoscopy Division
130 Forbes Boulevard
Mansfield, Massachusetts 02766

Re: K073551
Trade/Device Name: Smith & Nephew Instrument Tray
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 30, 2008
Received: May 1, 2008

Dear Ms. Acker:

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" (21CFR 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K073551

Device Name: Smith & Nephew® Instrument Tray

Indications for Use: The Smith & Nephew instrument tray is intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The instrument tray is suitable for use in prevacuum steam and high temperature gravity steam sterilization methods.

The instrument tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Prevacuum Steam	132°C – 135°C (270°F-275°F)	4 minutes	30 minutes
High Temperature Gravity Steam	132°C (270°F)	10 minutes	70 minutes

Device model that is the subject of this pre-market notification:

REF	Description
72201731	Tray, ACUFEX® DIRECTOR ELITE® Drill Guide Systems

Prescription Use _____ AND/OR Over-The-Counter Use __X__

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073551