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SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY

Date Prepared: August 19, 2009

A. Submitter's Name:

SEP 14 2010

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

B. Company Contact

Christina Flores
Regulatory Affairs Specialist II
T: 508-261-3705
F: 508-261-3620
Christina.flores@smith-nephew.com

C. Device Name

Trade Name:	Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories
Class:	II
Product Code:	KCT
Classification Number:	21 CFR §880.6850

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D. Predicate Devices

The subject Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew Instrument Tray cleared under K073551, Smith & Nephew Instrument Trays cleared under K090562, and Smith & Nephew Instrument Trays cleared under K091627.

E. Description of Device

The Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY is a reusable stainless steel sterilization tray and lid fitted with a silicone pin mat and instrument holders designed to contain and protect reusable surgical instruments during transport, sterilization, and storage. Perforations in the tray and lid allow for optimal exposure of the tray's contents to sterilant during the sterilization process.

F. Intended Use

Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAYS are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The instrument trays are suitable for use in a prevacuum steam method. They are 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
Pre-vacuum steam	132 C (270 F)	4 minutes	60 minutes

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

REF	Description
72202441	Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY

G. Comparison of Technological Characteristics

The technological characteristics of the proposed Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY are identical to the predicate devices. The material of construction, the type of instruments contained, and the intended use are unchanged from the predicate trays. The internal configuration and number of instrument holders, pin mats, and organizing racks differ to accommodate each trays designated instrument set. These differences do not represent new technological

characteristics for the proposed device and therefore do not raise new questions of safety or efficacy.

H. Summary Performance Data

Non clinical validation testing was conducted for sterilization and functional strength in order to demonstrate that the subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Performance testing was conducted in accordance with AAMI ST77:2006 *Containment Devices for reusable medical device sterilization* and demonstrates substantial equivalence to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Christina Flores
Regulatory Affairs Specialist II
Smith & Nephew, Incorporated
150 Minuteman Road
Andover, Massachusetts 01810

SEP 14 2010

Re: K092551
Trade/Device Name: Smith & Nephew Instrument Trays
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: KCT
Dated: September 3, 2010
Received: September 7, 2010

Dear Ms. Flores:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092551

INDICATIONS FOR USE STATEMENT

510(K) Number:

Device Name: Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAY

Indications for Use: Smith & Nephew ACUFEX™ GRAFTMASTER™ III SYSTEM TRAYS are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The instrument trays are suitable for use in a prevacuum steam method. They are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameter:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	132 C (270 F)	4 minutes	60 minutes

Device models that are the subject of this pre-market notification:

REF	Description
72202441	Smith & Nephew Acufex Graftmaster III System Tray

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

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

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

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

510(k) Number: K092551