510(k) Summary
for
Surgetics ENTact Endonasal Navigation System

1. Submitter Name and Address
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“Le Grand Sablon”
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Contact Name: Stéphane Lavallée
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Date Prepared: July 10, 2002

2. Device Name
Proprietary Name: Surgetics ENTact Endonasal Navigation System
Common/Usual Name: Image guided surgical navigation system
Classification Name: Computed tomography x-ray system (accessory)

3. Predicate Device
Marconi Medical Systems Voyager (K00310)

4. Intended Use
The Surgetics ENTact Endonasal Navigation System is intended for use as an aid to the surgeon for precisely locating anatomical structures either during open or percutaneous ENT/endonasal or sinus procedures.

5. Device Description
The Surgetics ENTact Endonasal Navigation System is specifically designed for use in ENT/endonasal and sinus procedures. It allows the surgeon to locate surgical instruments (e.g., aspirator) on three planes (axial, sagittal, frontal) on a pre-operative CT scan in real-time. The system uses an infrared camera for localization and guidance of the surgical instrument. Additionally, a surgical planning capability
using the Consultics Station is provided which allows the surgeon to pre-operatively plan the surgery.

6. **Technological Characteristics and Substantial Equivalence**

The Surgetics ENTact Endonasal Navigation System is substantially equivalent to other predicate image-guided systems (e.g., Marconi Voyager, K000310) that are currently marketed. It is similar to the other image-guided systems in its technological characteristics. It uses the same type of optical infrared system for instrument tracking and localization as other previously cleared image-guided systems. Like the predicate products, it includes tools and accessories that are used during the procedure and require sterilization prior to use. The various predicate image-guidance systems use a variety of methods for registration of the alignment of the patient with an image. The Surgetics uses a frameless system that doesn’t require pre-operative scanning of fiducial markers. Registration is achieved prior to surgery by simply mapping multiple points or areas on the patient’s face using a special ball pointer mapping probe. The mapped points are then registered with the corresponding points on a 3-D CT image of the patient’s face.

7. **Performance Testing**

The Surgetics ENTact Endonasal Navigation System was tested for compliance with electrical safety and electromagnetic compatibility standards. In addition, summaries of accuracy testing using phantoms and clinical experience with the system were provided.
Dear Ms. Hemeon-Heyer:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

- 8xx.1xxx               (301) 594-4591
- 876.2xxx, 3xxx, 4xxx, 5xxx  (301) 594-4616
- 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx  (301) 594-4616
- 892.2xxx, 3xxx, 4xxx, 5xxx  (301) 594-4654
- Other                    (301) 594-4692

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" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known):

Device Name: Surgetics ENTact Endonasal Navigation System

Indications for Use:

The Surgetics ENTact Endonasal Navigation System is intended for use as an aid to the surgeon for precisely locating anatomical structures either during open or percutaneous ENT/endonasal or sinus procedures.

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  /  OR  Over-The-Counter Use  
(Per 21 CFR 801.109)  

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