Points to Consider for Marketing of Computerized Surgical Systems in the U.S.

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Outline

- FDA Regulatory Perspective
- Marketing Applications with examples
- Non-marketing applications
- Summary

FDA Regulatory Perspective

- Risk based determination
- Class I, II and III, with III being subject to the highest level of control
- Defines the level of regulatory oversight

Regulatory 'Tools' for the Approval Process

- Premarket Approval Applications (PMAs)
- Humanitarian Device Exemption (HDEs)
- Premarket Notifications [510(k)s]
- Investigational Device Exemptions (IDEs)

Marketing Applications

- Premarket Approval Applications (PMAs)
  - Class III devices
  - 30 – 50 original PMAs applications each year
  - $259K - $98K filing fees (FY06)
- Humanitarian Device Exemption (HDE)
  - “Orphan” products < 4,000 pts/yr
  - Demonstrate safety, probable benefit
  - 10 – 20 applications each year
  - $0

Four Stages of PMA review

- Filing Review
- Substantive Review
  - Includes one or more cycles
  - May also include a prior module review
- Panel Process
- Closeout Process

ExAblate 2000 System

- A phased array high intensity focused ultrasound system with MR imaging.
- The ultrasound energy is focused through the abdomen to target tissue in the uterus.
- Results in thermal ablation of tissue.

Intended Use

- Intended for ablation of uterine fibroid tissue in pre- or peri-menopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.
- New intended use and new technology
- PMA (P040003)

Pre-Clinical Studies

- Electrical Safety
- Electromagnetic Compatibility
- Software Life Cycle Development
- Ultrasound charateristization
  - Focusing of the transducer
  - Transducer power measurement
  - Generation of larger focal regions
  - Cavitation detection
  - Detection of acoustic coupling
  - MR thermometry
  - Adequate cooling time

Clinical Studies

- Feasibility Study
  - Safety
  - Tissue effect (thermocoagulation)
- Pivotal Study
  - Safety and effectiveness for the treatment of uterine fibroids

Time Line to PMA approval

Marketing Applications

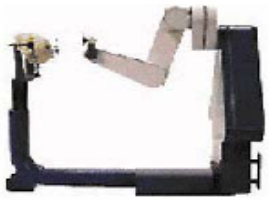
- Premarket Notifications [510(k)s]
  - Primarily for class II devices
  - 3000 – 4000 510(k)s submissions each year
  - $3800 - $3000 filing fees (FY06)

510(k) Review

- Substantial Equivalence or Comparison to a legally marketed device (s) (predicates)
  - Same intended use and same technology characteristics, or
  - Same intended use and different technology characteristics that does not raise new types of questions of safety and effectiveness

INTEGRATED SURGICAL SYSTEMS

Redefining Surgery ... ... around the World!



NeuroMate™

NeuroMate™ is an image-guided, computer-controlled, robotic system for stereotactic functional brain surgeries. It also includes a pre-surgical planning workstation. The NeuroMate System positions, orients and manipulates the operating tools within the surgical field exactly as planned by the surgeon on the image planning workstation. The system interacts with the surgeon during surgery and adapts to the changes required during the surgery.

Products
Investors
Press Rele
Contact IS

The first generation NeuroMate System required the use of cumbersome and painful head frames that are traditionally used in the current manual techniques for brain surgeries. The proprietary "frameless" technique of ISS altogether eliminates the need for cumbersome and painful head frames.

eMail: ISS Info
06/08/02

NeuroMate Stereotactic System

- Indicated for stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.
- Same intended use and similar technology
- 510(k)

NeuroMate Stereotactic System

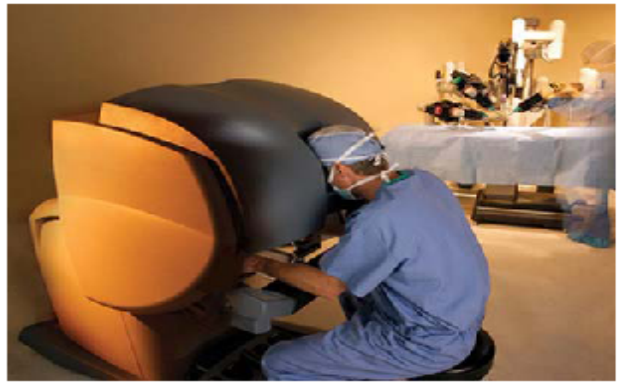
- System description
- Electrical safety tests
- EMC tests
- Software Life Cycle Development
- Mechanical performance tests
- Clinical test
- Training

INTUITIVE SURGICAL®

search

The *da Vinci*® Surgical System

The *da Vinci* Surgical System consists of an ergonomically designed surg console, a patient-side cart with four interactive robotic arms, the high-performance *InSite*® Vision System and proprietary *EndoWrist*® Instrum Powered by state-of-the-art robotic technology, the surgeon's hand move scaled, filtered and seamlessly translated into precise movements of the Instruments. The net result: an intuitive interface with breakthrough surg capabilities.



Components of the *da Vinci* Surgical System

Surgeon Console

Using the *da Vinci* Surgical System, the surgeon operates while seat comfortably at a console viewing a 3-D image of the surgical field.

The surgeon's fingers grasp the master controls below the display, w and wrists naturally positioned relative to his or her eyes.

The system seamlessly translates the surgeon's hand, wrist and fing movements into precise, real-time movements of surgical instrumen

Clinical Validation

Cardiac
"The *da Vinci* System makes it possible to offer a wider range of patients a minimally invasive open-heart procedure to repair the mitral valve. This will allow more patients to benefit from both shorter hospital stays and reduced recovery times."

W. Randolph Chitwood, Jr. M.D.
Professor and Chairman Department of Surgery
Chief of Cardiothoracic Surgery
East Carolina University School of Medicine

Urology
"As a trained surgical oncologist, *da Vinci* has allowed me to offer my patients a better cancer operation with improved clinical outcomes."

Thomas E. Ahlering, M.D.
Associate Professor of Urology
Director, Urological Oncology
University of California Irvine Medical

da Vinci Surgical System

- Intended to assist in the accurate control of Intuitive Surgical endoscopic instruments including ... during laparoscopic surgical procedures such as cholecystectomy or Nissen fundoplication. It is intended for use by trained physicians in an operating room environment.

- New intended use and similar technology

da Vinci Surgical System

- System description
- Electrical safety tests
- EMC tests
- Software Life Cycle Development
- Mechanical performance tests
- Pre-Clinical test
- Clinical test
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Non-Marketing Applications

- Investigational Device Exemptions (IDEs)
  - Intent to study
    - New intended use of approved device; or
    - New device
  - FDA approval of an IDE required?
    - Significant Risk -- yes
    - Nonsignificant Risk – no
  - $0

Others

- 513g Request is a written request to FDA to determine:
  - Medical device or not?
  - Classification (Class I, II or III)
- Combination Products as defined under 21 CFR 3.2(e)
  - Product that combines two or more regulated components (i.e. drug-eluting stent)
  - Primary mode of action

Thank you - Arigato

- Please stop by my poster 075 if you have any additional questions.