FDA and Optical Imaging Device/Combinations

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Notice of Conflicts

None

I currently work for FDA.
Disclaimer

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Presentation Overview

- What we have done
- What we want to do
- How we can do it
- Considerations
Who does What at FDA?
Light based Imaging and Combination products
Cleared Device Indications with ICG

1. For use in intra-operative visual assessment of the coronary vasculature and bypass grafts during coronary artery bypass (CABG) surgery.

2. For visual assessment of blood flow and related tissue perfusion during cardiovascular surgical procedures.
3. For visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgery.

4. For visual assessment of blood flow as an adjunctive method for the evaluation of flow in the native and anastomosed vessels, tissue perfusion and related tissue-transfer circulation in implanted and surrounding organs; to visualize blood flow indicative of perfusion of the donor implant prior to transplantation and to provide indication of organ function after transplantation.
Cleared Device Indications with ICG, continued

5. For visual assessment of vessels, blood flow and related tissue perfusion with near infrared fluorescence imaging during minimally invasive surgery.

6. For visual assessment of vessels, blood flow, and related tissue perfusion with near infrared fluorescence imaging during minimally invasive robotic surgery.

7. For visual assessment of blood flow and related tissue perfusion during gastrointestinal surgery.

8. For use as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.
9. For use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

10. Intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical tract; enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion.

11. The da Vinci Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci® Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extrahepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.
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What Imaging Clinical Strategy?

Complex issues dependent on many variables:

- General visualization alone
- Specific disease detection
- Combination products
Devices indicated for imaging specific diseases

Device Indication drives data needs.

Stand alone clinical data showing S&E will be needed.
Devices indicated for margin detection

When and where is margin detection occurring?
Imaging Combination products

Device plus drug or biologic will be reviewed together.

Combination products: Complicated
Likely - stand alone clinical data showing Safety & Effectiveness.

If there’s a predicate – technical comparison.
Regulatory Pathway:

- Established Drug, same dosing, admin. Route - 510(k) or PMA. (ICG, Sodium Fluorescein)
- New Molecular Entity – New Drug Application (NDA)
- New drug indication - NDA or supplements
Combo Product - Which Center has lead - RFD?

Request For Designation (RFD) to our Office of Combination Products (OCP) will review Primary Mode of Action and how the combination achieves its Primary Intended Purpose(s) and what are the major FDA review challenges.
OCP Guidance

Copies are available from:

Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930 (Fax) 301-847-8619
http://www.fda.gov/CombinationProducts/default.htm.
Informational needs for FDA device review

- Device Labeling
- Performance specifications
- Valid scientific evidence
- Tissue effects
- Mechanism-of-Action, like to have
- Clinical outcomes
(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.
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Phantoms
Standardization Efforts for Optical Imaging

Consensus standards are corner stones for other imaging modalities, serving both the industry and the government agencies.

Increasing needs to standardize aspects of optical imaging - to facilitate product/clinical trial development.
What to standardize?

- Optical Image calibration and performance evaluation
- Optical Image quality, # pixels, color rendering
- Optical Image size, resolution, contrast, precision
- Optical Image capture, CCD, ICCD, ultrasound, OCT, photoacoustic
- Optical Image creation
Optical imaging technology ---- non-ionizing, real-time microscopic observation
An emerging field in medical applications, particularly coupled with general surgery / minimally invasive surgery
Based on technologies and indications, regulated as Class I, II, and III devices
Specific disease detection, e.g., cancer, in screening and for intraoperative guidance
Challenges for combination products regulatory route with new drugs or approved drugs – across-Center efforts with CDER, CBER, and with Office of Combination Products
THANK YOU
For your Attention!
Extra slides
Questions ?