What is happening with vascular device evaluation and approval at the FDA: How is it helping vascular surgeons develop and get to use new devices?

Dorothy B. Abel
Dorothy.Abel@FDA.HHS.GOV
Center for Devices and Radiological Health
Office of Health Technology 2 | Division of Health Technology 2B
Vascular and Endovascular Devices Team

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Outline
• Pilot reorganization
• Customer service
• Applying least burdensome principles
  – Identifying the information needed to support device and labeling modifications
• De Novo reviews
• Early Feasibility Study Program
• Breakthrough Devices Program

Total Product Life Cycle Transformation
• New approach to how the Center for Devices and Radiological Health (CDRH) conducts business and the way it is structured
  • Increase information-sharing across CDRH by eliminating intra-organizational silos
  • Enhance collective decision-making
  • Improve work-life balance
  • Increase professional opportunities for employees
• Holistic approach that takes into account all of the steps and processes that lead to the design, production, use and impact of safe, effective and high-quality medical devices

Pre-reorganization Structure
Center for Devices and Radiological Health
• Office of Device Evaluation (ODE)
  – Division of Cardiovascular Devices (DCD)
  • 8 review branches (e.g., Vascular Surgery Devices Branch (VSDSB))
  – 6 other review divisions and 1 support division
• Office of Compliance (OC)
• Office of Surveillance and Biometrics (OSB)
• Office of In Vitro Diagnostics and Radiological Health (OIR)
• 3 others

Pilot Structure
Office of Product Evaluation and Quality (OPEQ)
(Incorporates offices formerly known as ODE, OC, OSB, and OIR)
• Office of Health Technology 2
  (Integrates staff from the division formerly known as DCD, with some OC and OSB staff)
  – Divisions of Health Technology 2A, 2B and 2C
    (Groups the previous DCD review branches as review teams, e.g., the Vascular and Endovascular Devices Team)
• 6 other device-specific offices (including OIR) and 2 supporting offices

Financial Disclosure Slide
• I have nothing to disclose
Vascular Device Evaluation and Approval

- Most review teams align with pre-reorg branches
  - Most devices reviewed by VSDB are still regulated by the new Vascular and Endovascular Devices team
  - Cross-communication is encouraged between divisions and teams
- Customer service remains a priority

Pre- and Post-Market Balance

- For device modifications, identify the potential impact of the modification on device performance and the data needed to support the change
  
  Example: Valiant Navion approved based on 30-day pre-market clinical data with 1-year data to be provided post-approval

Use of Real World Evidence (RWE)

- Used to expand indications for use
  
  Example: Approval of Endurant for short necks when used with Heli-FX
  
  - Considering the use of RWE to remove warnings regarding devices not having been evaluated in certain populations
  
  Example: May remove warnings regarding chronic dissections or ruptured aneurysms

  NOTE: Changes in labeling may not affect practice of medicine, but may improve medico-legal and reimbursement environments.

De Novo Program

- For devices that would be appropriately regulated under the 510(k) process (less burdensome than the Premarket Approval process) but no legally marketed predicate device exists
- Involves submitting a De Novo request
- If granted, the new device can serve as a predicate for 510(k) submissions of future devices of the same type

Examples: EverlinQ endoAVF System and Ellipsys Vascular Access System granted De Novos for percutaneous AVF creation

Early Feasibility Study Program

- Provides early access of investigational devices to US patients, often intended to address unmet clinical needs
- Basic philosophy of doing the right testing at the right time, that is, supporting IDE initiation with the appropriate information given the clinical context and potential for device modifications during the study

Example: Many EFS, including first-in-human, manufacturer-sponsored and sponsor-investigator IDEs for devices intended to treat complex aortic anatomies

Customer Service Examples

- Help with drafting Sponsor-Investigator (SI) Investigational Device Exemptions (IDE) applications
- Interact with sponsors and research personnel to address regulatory requirements and questions
- Identify least burdensome approaches to obtain access to vascular devices
  - Pre- and post-market balance
  - Use of real world evidence
Breakthrough Devices Program*

• Voluntary program for certain devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
• Intended to help patients have more timely access to these devices

Examples: Look for public disclosures, such as the Boston Scientific SALVAL Trial

*Covered in 2017 VEITH presentation

How are we helping vascular surgeons develop and get to use new devices?

• Reducing regulatory-associated delays
  — Supporting sponsor-investigators
  — Optimizing customer service through interactive assistance and review
  — Identifying and applying least burdensome approaches to evaluate new and modified devices
  — Utilizing De Novo, Early Feasibility Study, and Breakthrough Devices Programs

Resources

• Evaluation of Automatic Class III Designation (De Novo) Summaries
  https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm232269.htm
• Early Feasibility Study Guidance
• Breakthrough Devices Program, Draft Guidance for Industry and Food and Drug Administration Staff (Oct. 2017)