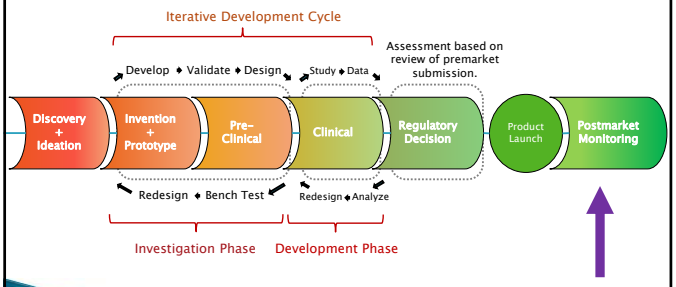
FDA Regulation of Medical Devices
Postmarket Requirements

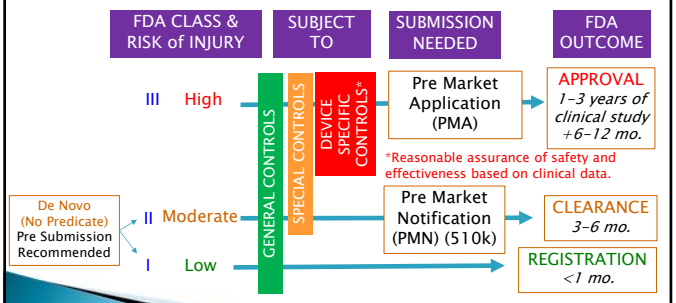
Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

Medical Device Development Pathway



Adopted from CDRH *Innovation Initiative*, February 2011.

Recap of Authorization Pathways



Postmarket Requirements

- Postmarketing Surveillance and the National Evaluation System for Health Technology (NEST)
  - Postmarket Surveillance Studies ("522 Studies")
  - Adverse Event Reporting
  - Medical Device Tracking
  - The Sentinel Initiative
  - Unique Device Identification (UDI) System

Johnson, J. A., *FDA Regulation of Medical Devices*, 2016

Postmarket Surveillance Studies

- Monitors the on-going safety.
- Corrective actions
  - Changing the device labeling.
  - Changing the instructions for use.
  - Improving user training.
  - Removal of the device from the market if appropriate.
- Issues
  - Some foreign surveillance systems have identified serious device safety concerns sooner than in the United States.
- Additional Benefit
  - Understanding and measuring device innovation and cost-effectiveness

- Information sources:
  - Medical Device Reporting (MDR).
    - *Adverse Event Reporting* within 30 Days by manufacturer.
    - Annually hundreds of thousands of reports of confirmed or possible medical device related malfunctions, serious injuries, and deaths.
  - Medical Product Safety Network (MedSun).
    - Network of 280 US hospitals ~5,000 reports annually.
  - Post-Approval Studies –
    - May be a condition of PMA approval.

- 522 Postmarket Surveillance Studies (Class II and III Devices).
  - If failure may cause serious consequences.
  - If intended for significant use in pediatrics.
  - Intended to be implanted >1 year.
  - Life-supporting or sustaining outside a device user facility.
- FDA Discretionary Studies.
  - FDA conducts its own research
  - Use of privacy-protected data- National registry, Medicare & Medicaid, EHR and literature.
- National Evaluation System for health Technology (NEST)
- Real World Data (RWD)
  - Data collected outside of traditional clinical trials.

Medical Device Tracking

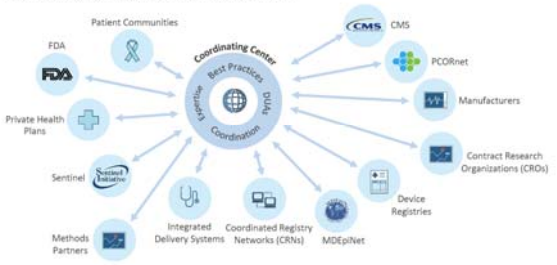
- FDA may issue a *tracking order* for any Class II or Class III device if:
  - If failure may cause serious consequences
  - Intended to be implanted <1 year
  - Life-supporting or sustaining outside a device user facility.

The Sentinel Initiative

- Launched in 2008
- Postmarket risk identification system
  - Monitoring all FDA regulated products – drugs and medical devices after they have reached the market.
  - As of 2012 there was secure access to data from ~126 million patients.
  - Health partners: academic medical centers, healthcare systems and health insurance companies.

National Medical Device Evaluation System…

Figure 1. NMDES as a Coordinated Network of Partners



NMDES, Duke-Margolis Center Planning Center Report. April, 2016.

Table 2. Objectives of the NMDES Coordinating Center

Coordinating Center Objectives	Description
Functional Objectives	
Optimize the cost of, access to, quality of, and sharing of data related to the evaluation of medical devices	The Coordinating Center should create a coordinated network of data partners by promoting UDI adoption, standardized data sharing agreements, interoperability, and automated data collection and extraction while committing to rigorous privacy, ethical, and data security protections.
Promote the adoption of best practices for device evaluation	The Coordinating Center should develop a clearinghouse of best practices for evaluating the safety and efficacy of medical devices that is easily accessible to researchers and the public.
Develop a transparent and streamlined process for evaluating and disseminating medical device safety and effectiveness information	The Coordinating Center should promote methods for evaluating emerging safety signals and the dissemination of accurate and informative safety information to patients, clinicians, and policymakers in a responsible, timely, and accurate manner.
Organizational Objectives	
Establish governance components for NMDES and the Coordinating Center	A governing board, expert committees, and an executive director will need to be identified and selected by the Coordinating Center early on. The governing components will be critical towards setting the policy agenda for NMDES activities.
Develop a sustainable business model for a national medical device evaluation system	The Coordinating Center should be the central body responsible for promoting the long-term sustainability of NMDES through both public and private funding sources.

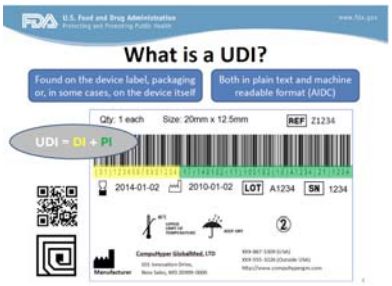
NMDES, Duke-Margolis Center Planning Center Report. April, 2016.

Figure A1. Essential Uses of a National Medical Device Evaluation System

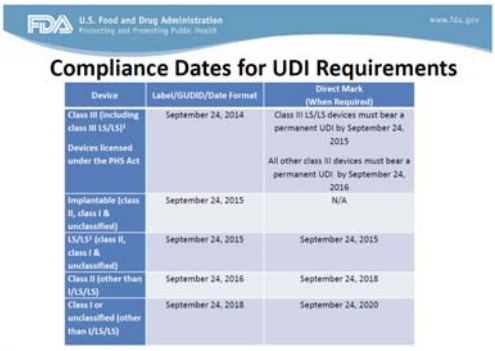
- Safety surveillance to support evidence-based decision-making, recall management, and safety communication.
  - Active safety surveillance
  - Passive safety surveillance
  - Recall management
  - Safety communication
- Activities to meet specific FDA evidentiary requirements
  - Studies to support premarket submissions
  - Post-Approval Studies
  - 522 Postmarket Surveillance Studies
  - Discretionary studies
  - Indication expansions
  - Label changes
  - Fostering appropriate shifts of premarket data collection to the postmarket setting

NMDES, Duke-Margolis Center Planning Center Report. April, 2016.

Unique Device Identification



Prof. Steven S. Saliterman



Device	Label/GUDID/Date Format	Direct Mark (When Required)
Class III (including class III LS/LS)[1] Devices licensed under the PHS Act	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS[2] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24, 2020

Prof. Steven S. Saliterman

Other Requirements

- Labeling:
  - All labels and accompanying printed matter – *including advertising*.
- Manufacturing
  - Good Manufacturing Practice (GMP) (as described in the Quality System (QS) regulations)
- Compliance and Enforcement
  - Inspection
  - Warning Letter
  - Product Recall

Prof. Steven S. Saliterman

Johnson, J. A., *FDA Regulation of Medical Devices*, 2016

Recent Literature

Clinical Review & Education

JAMA Internal Medicine | Special Communication

Renewing the Call for Reforms to Medical Device Safety—The Case of Penumbra

Kushal T. Kadakia, MSc; Adam L. Beckman, BS; Joseph S. Ross, MD, MHS; Harlan M. Krumholz, MD, SM

Editorial page 8

Supplemental content

IMPORTANCE Strengthening premarket and postmarket surveillance of medical devices has long been an area of focus for health policy makers. The recent class I recall (the most serious of the US Food and Drug Administration [FDA] recalls) of reperfusion catheters manufactured by Penumbra, a US-based medical device company, illustrates issues of device safety and oversight that mandate attention.

JAMA Intern Med. 2022;182(1):59-65. doi:10.1001/jamainternmed.2021.6626

Medical Device Recalls 2022

Feds find new heart pump defect

The troubled Medtronic device faces fresh recall; battery failure feared.

By BURL GILYARD
burl.gilyard@startribune.com

The U.S. Food and Drug Administration issued another

Minneapolis Star Tribune 6/24/2022

Smiths Medical pumps recalled

Minnesota-made syringe infusion devices linked to 1 death, 7 serious injuries.

By BURL GILYARD
burl.gilyard@startribune.com

These software problems led to seven serious injuries and one known death, according to the company.

Syringe pumps deliver precise amounts of blood, drugs, antibiotics and other therapeutic fluids through infusion tubing. According to the FDA recall notice, they are mostly used in neonatal and pediatric patients or operating rooms and intensive care units for adults.

Smiths Medical first issued a 15-page Urgent Medical Device Correction letter in

Minneapolis Star Tribune 7/21/2022

Medtronic calls back 1 million catheters

A single complaint spurs action for potential leak.

By BURL GILYARD
burl.gilyard@startribune.com

Medtronic has recalled more than 1 million catheters

Minneapolis Star Tribune 8/2/2022

Medtronic says pump for insulin vulnerable

The cybersecurity risk is the latest problem for the firm's diabetes business.

By BURL GILYARD
burl.gilyard@startribune.com

Minneapolis Star Tribune 9/21/2022

Summary

- Authorization Pathway
- Postmarket Requirements
  - Postmarket Surveillance Studies.
    - Adverse Event Reporting, Medical Device Tracking, UDI (Unique Device ID)
  - National Medical Device Evaluation System.
  - Labeling and Manufacturing
  - Compliance and Enforcement
- Medical Device Recalls 2022