Unique Device Identification (UDI): *Benefits of Adoption and Implementation*

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Congressional Authority

FDA Amendments Act, 2007

FDA Safety and Innovation Act, 2012

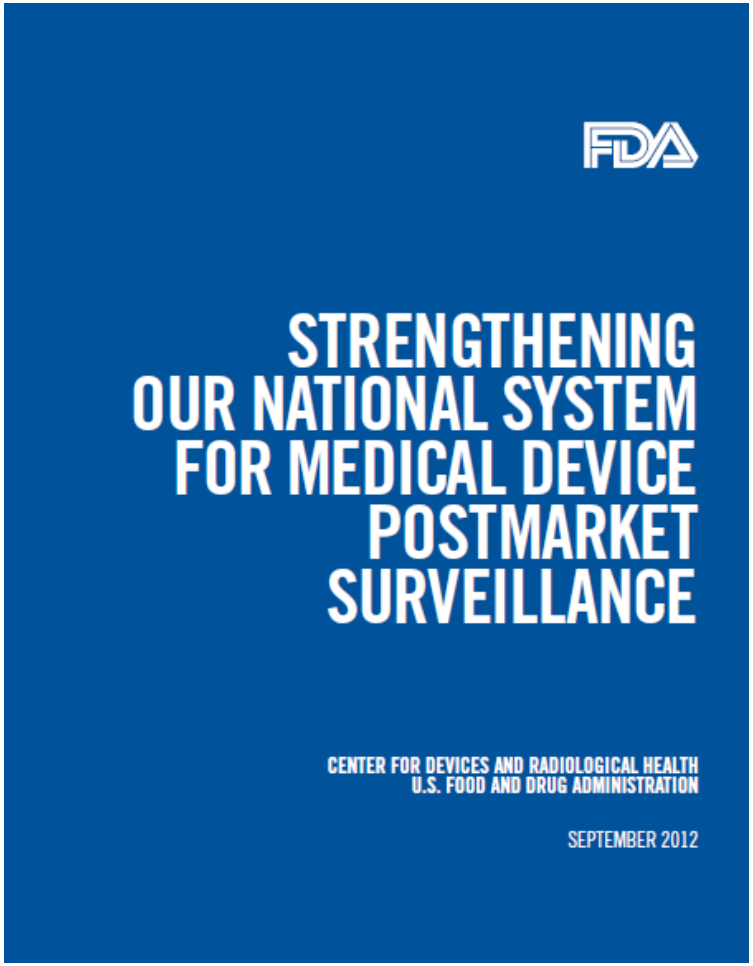
UDI Rule [78 CFR 58786], Sep 24, 2013

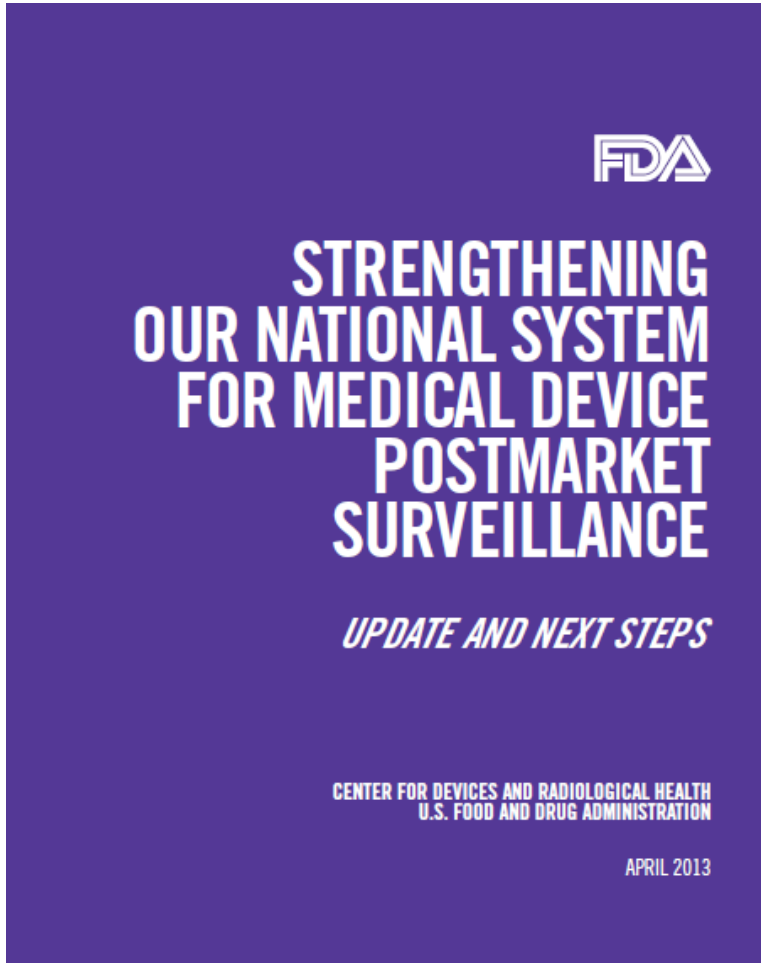
Benefits of UDI Final Rule

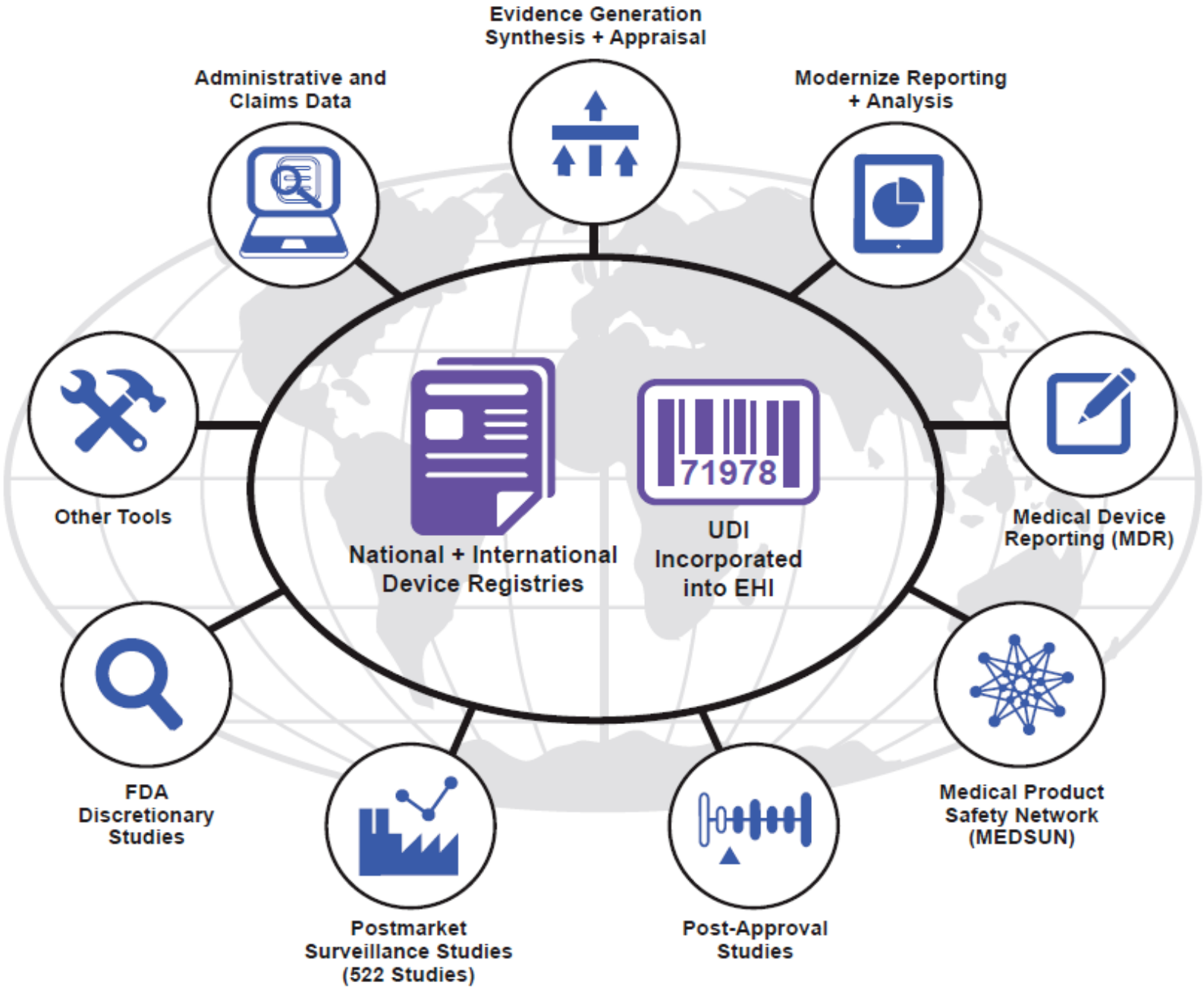
- Simplify integration in data systems
- More rapid and precise identification of medical devices
- Foundation for global, secure device supply chain
- Address counterfeiting and diversion and shortage issues
- Prepare for medical emergencies
- Reduce medical errors
- Facilitate more useful electronic patient records
- Pinpoint specific device in adverse events and recalls
- Better-focused and more effective FDA safety communication
- Support provision of high-quality medical services

Strengthening Our National System

Taking the Next Steps






Evidence Generation
Synthesis + Appraisal
Administrative and
Claims Data
Modernize Reporting
+ Analysis
Other Tools
National + International
Device Registries
71978
UDI
Incorporated
into EHI
Medical Device
Reporting (MDR)
FDA
Discretionary
Studies
Medical Product
Safety Network
(MEDSUN)
Postmarket
Surveillance Studies
(522 Studies)
Post-Approval
Studies

Key Benefits of UDI

Improve Patient Safety

More Accurate Understanding of Device Benefit-Risk Profile

Facilitate Device Innovation and Patient Access

Strengthening our National System for Medical Device Postmarket Surveillance
http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf

Establishing a UDI System

UDI Final Rule

[78 FR 58786]

Sept 24, 2013

- Develop a standardized system to create the UDI
- Place UDI on label and (sometimes) the device
- Create and maintain the Global UDI Database
- Adoption and Implementation

Additional Implementation Steps by FDA

- Support Brookings think tanks on steps to incorporate UDI into EHI – led to Roadmap
- Support Mercy demonstration project to assess UDI in hospital information systems
- Work with ONC towards voluntary certification of EHR technology that could capture UDI
- Phase-in UDI requirements through 2020

Implementation Timeframe

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III • Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Promote UDI Adoption

Standards

- Adapt standards and systems for UDI
- Enable UDI interoperability in technology

Capture

- UDI throughout Electronic Health Information
- Use UDI to improve care and affect workflow

Uses

- Connect the data and generate information
- Produce analytics for uses of real world data