Risk Management
&
the Total Product Life Cycle (TPLC)

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Objectives

1. Applicable Regulations, Standards, & Guidance Documents
2. The Important of Risk Management
3. Key Risk Management Terms & Definitions
4. Risk Management Process

Applicable Regulations, Standards, & Guidance Documents

- 21 CFR 820, Quality System Regulations
- ISO 13485:2016, Medical devices – quality management systems
- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- *Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions*

Applicable Regulations, Standards, & Guidance Documents

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- *Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics*
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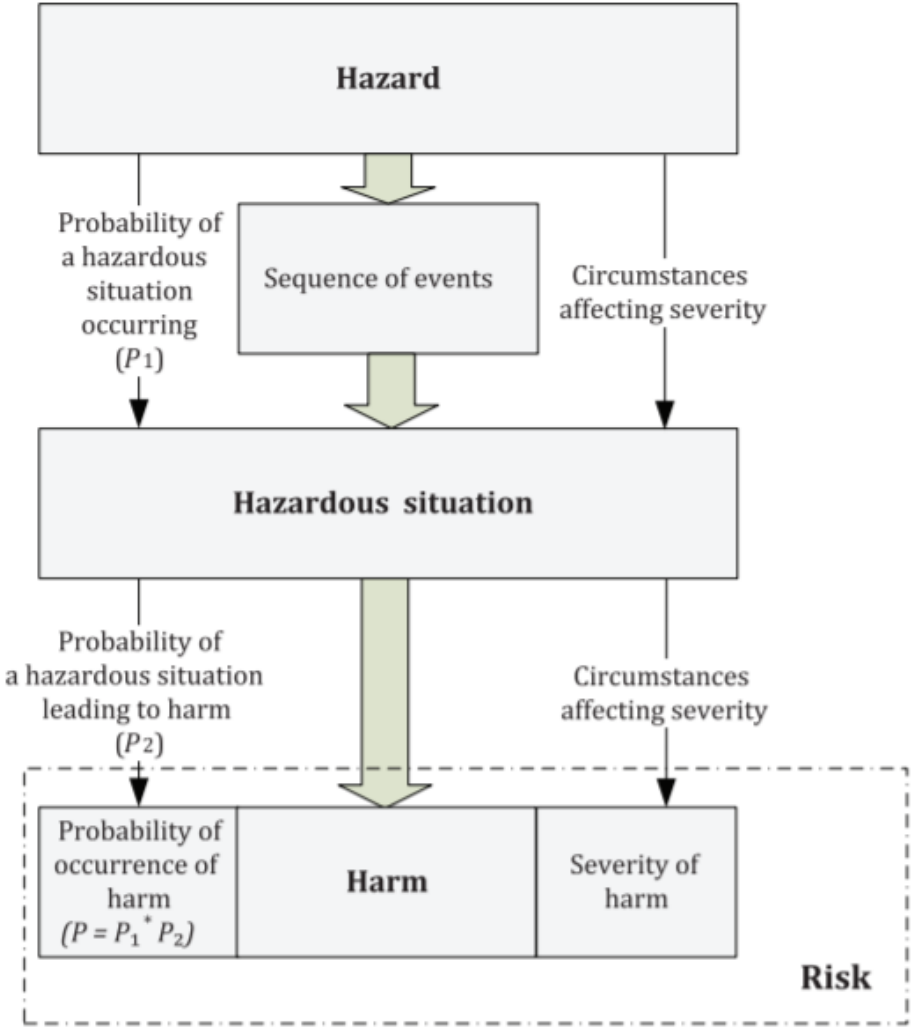
The Importance of Risk Management

The Importance of Risk Management

- Regulatory Requirement
- Required for Regulatory Submissions
- Good Business Practice & Cost Efficiency
- Safety

Key Risk Management Terms:

- **Risk**
  - The combination of the probability of occurrence of harm and the severity of that harm
- **Benefit**
  - Positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health
- **Harm**
  - Injury or damage to the health of people, or damage to property or the environment
- **Hazard**
  - Potential source of harm



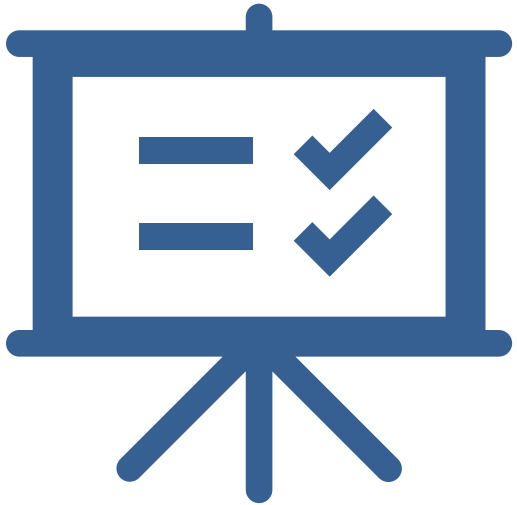
Source: ISO 14971:2019 Annex C

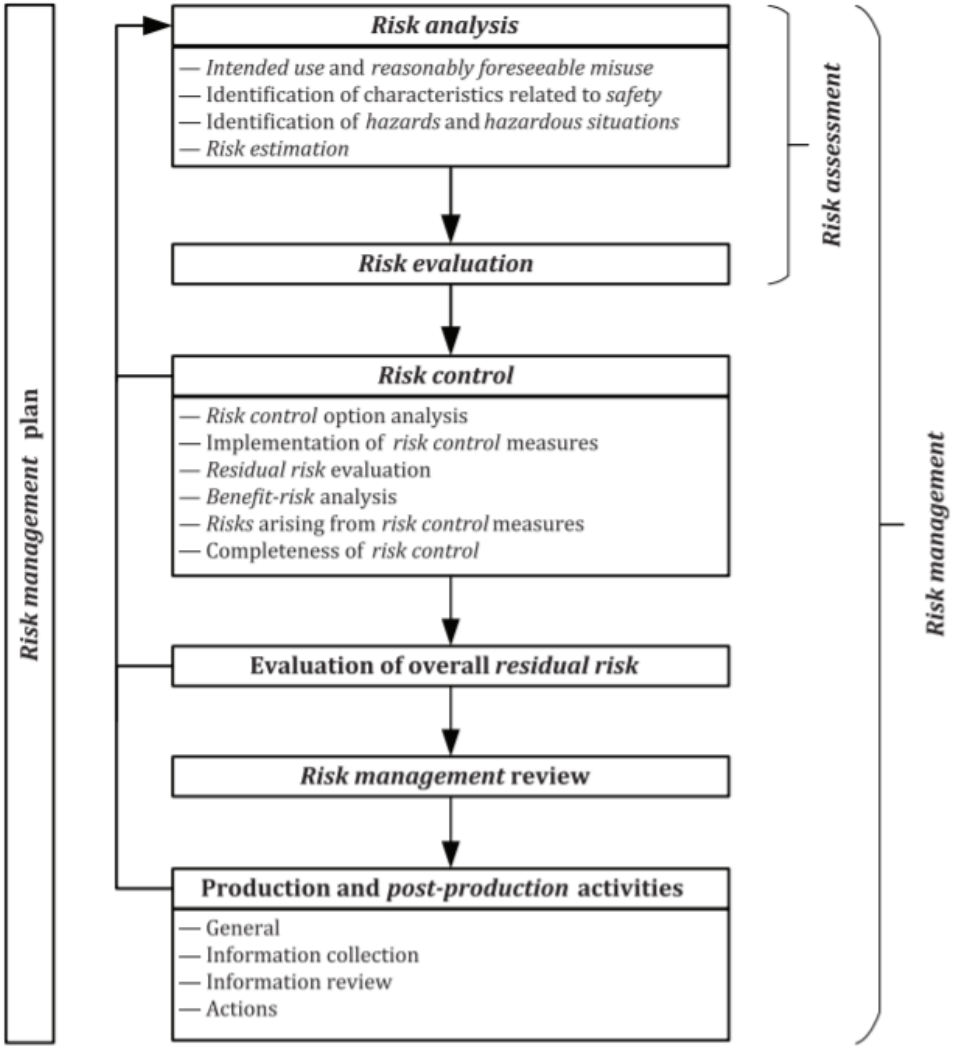
Key Risk Management Terms:

- Risk Analysis
  - Systematic use of available information to identify hazards and to estimate the risk
- Risk Evaluation
  - Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
- Risk Assessment
  - Overall process comprising a risk analysis and a risk evaluation
- Risk Management
  - Systemic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
- Life Cycle (TPLC)
  - Series of all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

Risk Management

Implementing a Process & Plan

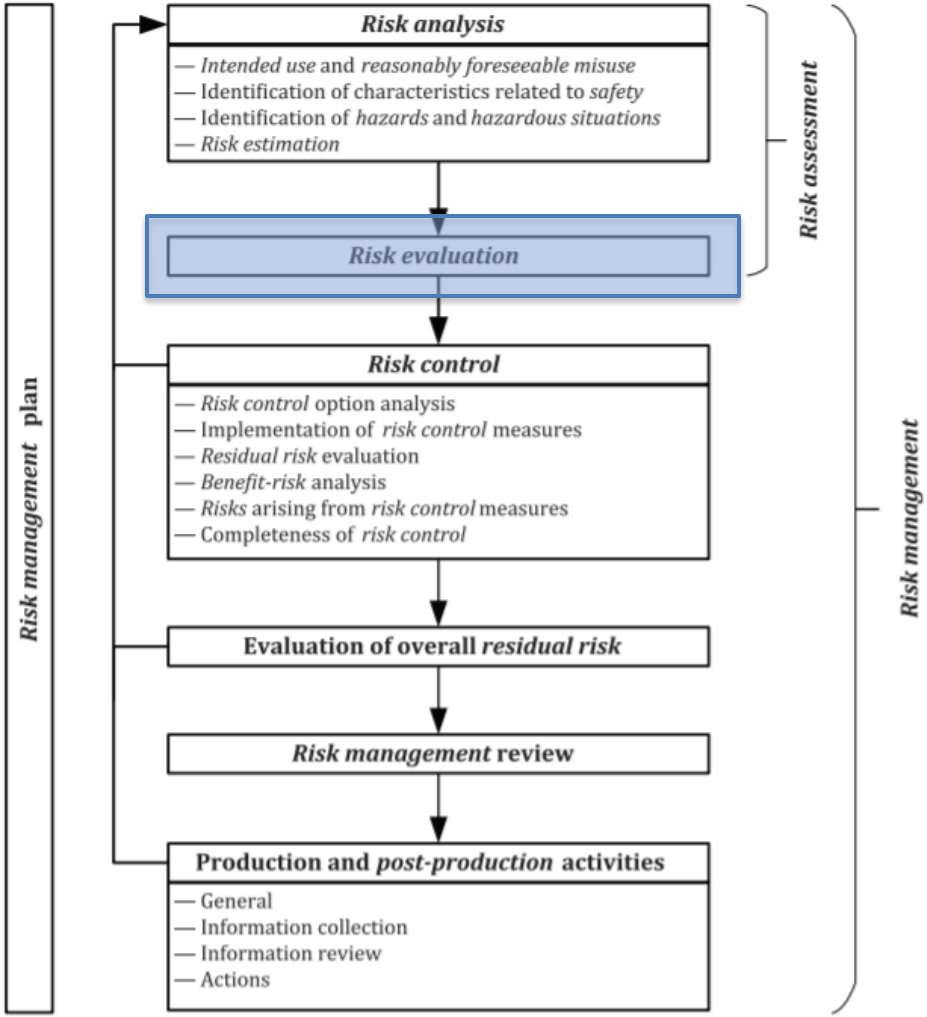




Source: ISO 14971:2019

Risk Analysis

- Intended use & reasonably foreseeable misuse
- Identification of characteristics related to safety
- Identification of hazards and hazardous situations
- Risk Estimation

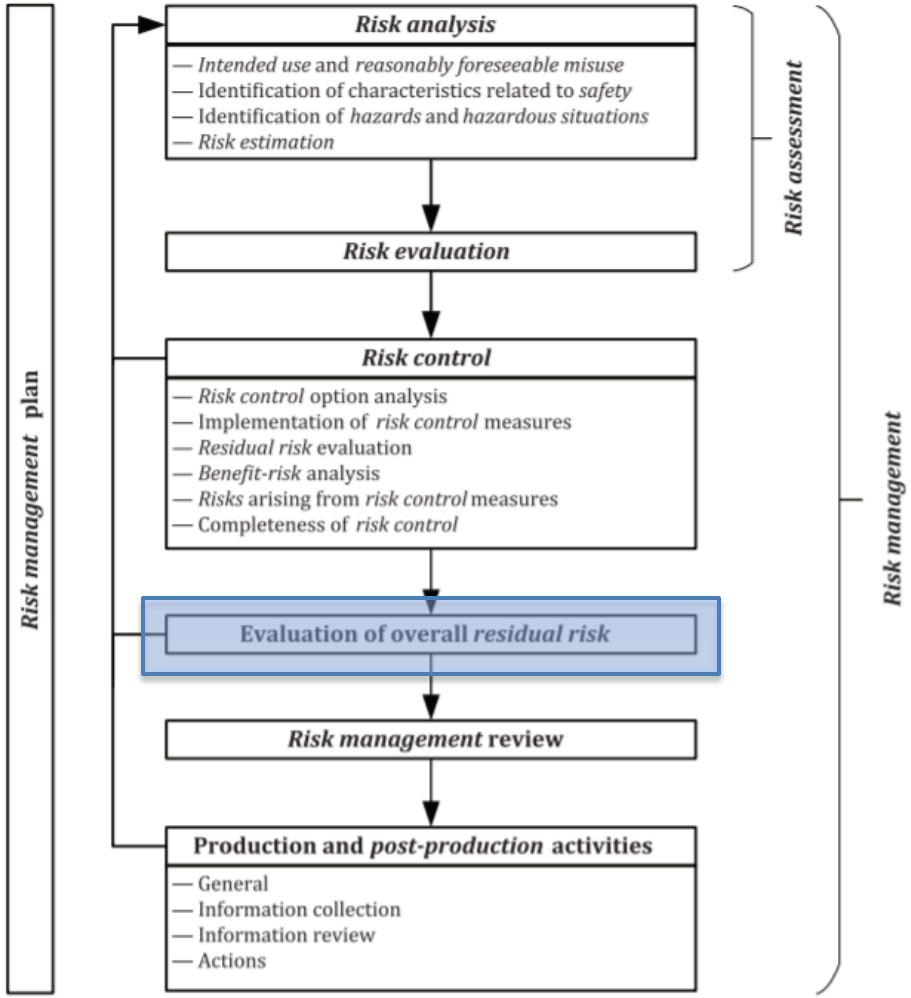


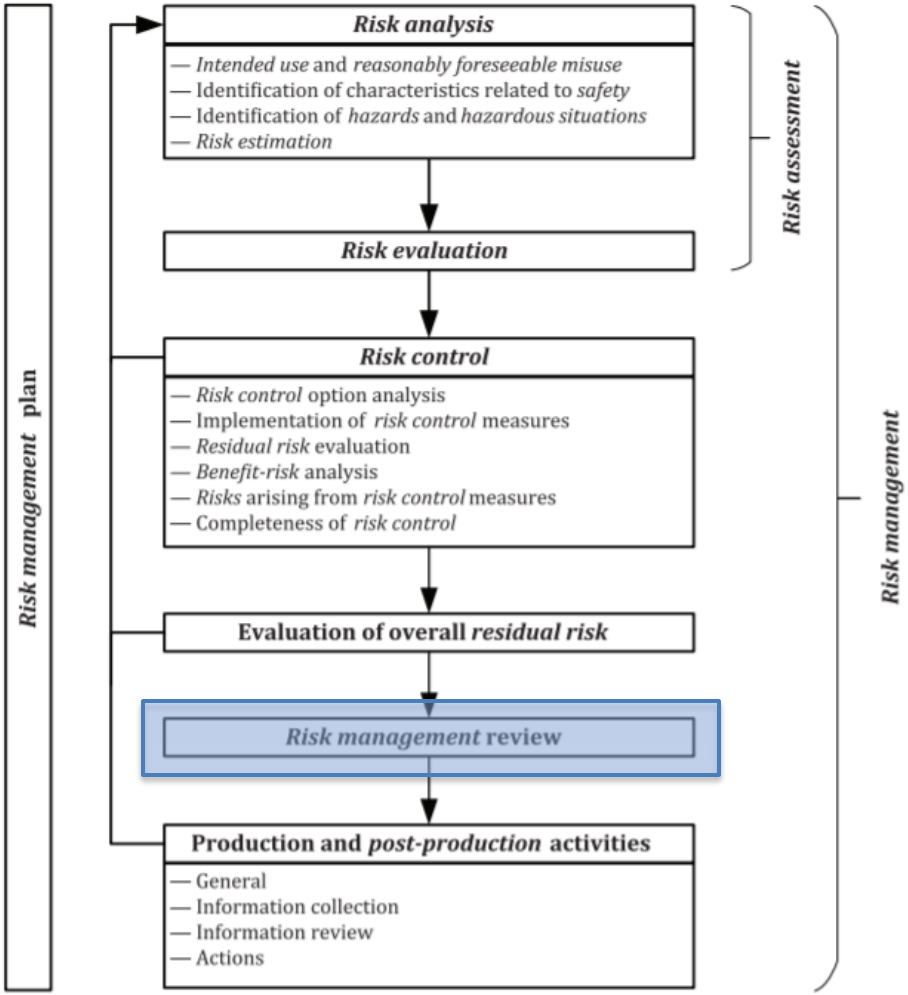
Risk Evaluation

Risk Control

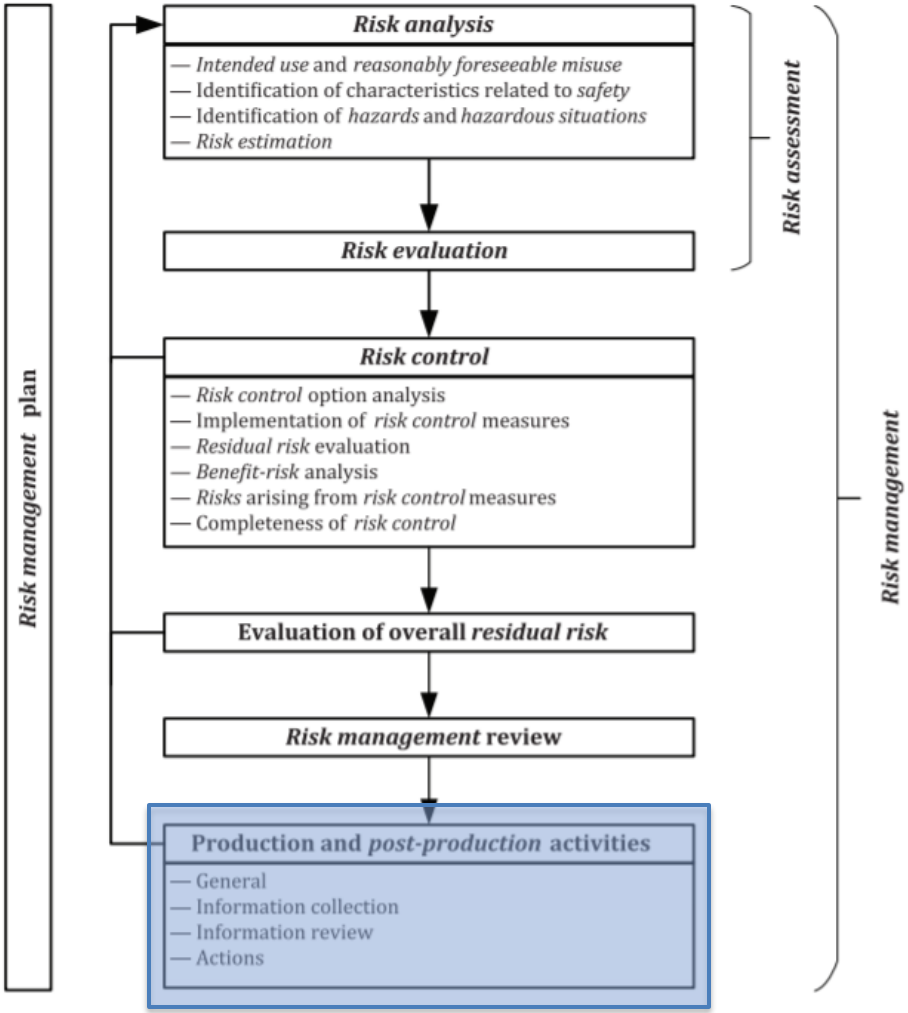
- Risk control option analysis
- Implementation of risk control measures
- Residual risk evaluation
- Benefit-risk analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of Overall Residual Risk





Risk Management Review



Production and Post-Production Activities

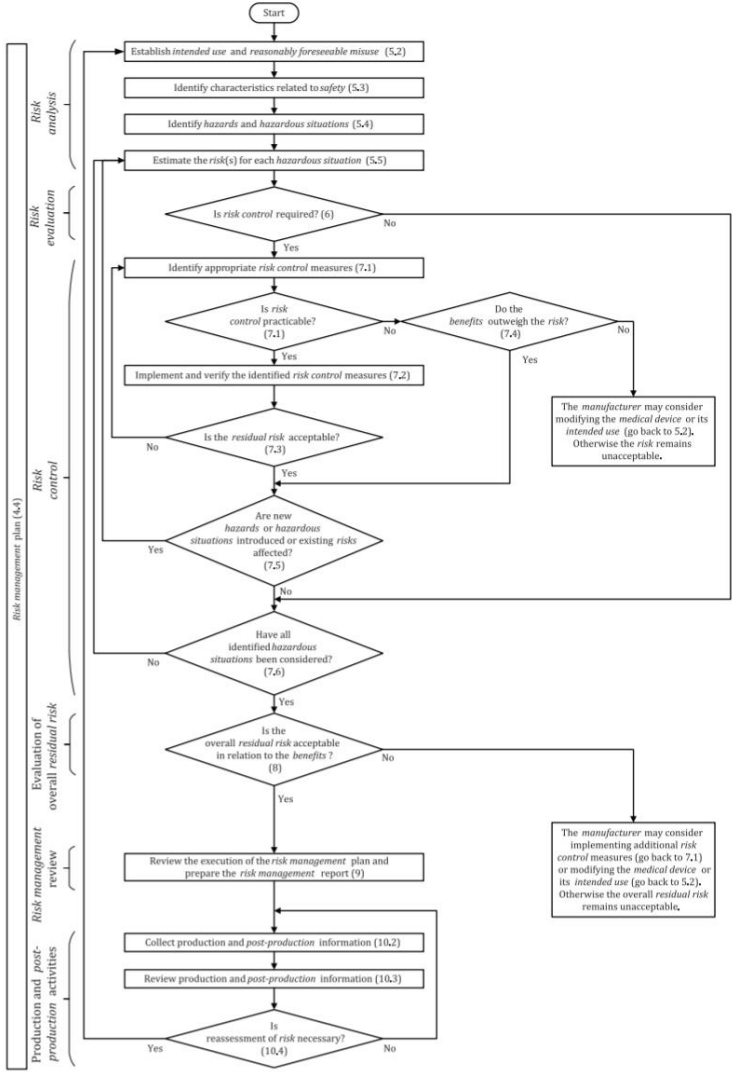
A.2.10 Production and *post-production* activities

It cannot be emphasized too often that *risk management* does not stop when a *medical device* goes into production. *Risk management* often begins with an idea, before there is any physical manifestation of the *medical device*. *Manufacturers* collect information from many sources, including experience with similar *medical devices* and technologies. *Risk estimation* is refined throughout the design *process* and can be made more accurate when a functioning prototype is built. However, no amount of modelling can substitute for an actual *medical device* in the hands of actual users.

Source: ISO 14971:2019 Annex A

Production and Post-Production Activities

- General
- Information Collection
- Information Review
- Actions



Source: ISO 14971:2019 Annex B

Contains Nonbinding Recommendations

Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 27, 2016.

The draft of this document was issued on June 16, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Compliance at 301-796-5900.

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Questions?


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