

MEDICAL DEVICE REGULATION – CONTROL BASED ON RISK

Fred S. Halverson

Medtronic, Inc.

Minneapolis, Minnesota

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RISK-BASED DEVICE CLASSIFICATION

- Appropriate classification
- Utility of classification schemes
- Flexibility of classification schemes



CONTROL BY REGULATORS

- Phases of control: Pre-market, Production and Post-market
- Types of control
- Different levels of control?



INDUSTRY PREFERENCE

- Quality systems, not testing
- Documentation review
- Transparency/access



LABELING/USE OF SYMBOLS

- Current requirements/industry compliance
- New requirements – Japan
- Standards/guidance
- Industry use of symbols



LOCAL LANGUAGE LABELING

- Current requirements
- Industry compliance
- When is it necessary/useful?
 - Compliance
- Labeling problems
- Examples



ROLE OF SYMBOLS

- Use of standards in regulation – advantages
- FDA, Canada, European Union procedures
- GHTF, Study Group I Guidance
- Certification
- International, national or other standards?

