# Conquer the MDR Maze: Expert Insights & Real-World Examples

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# Conquer the MDR Maze: Expert Insights & Real-World Examples

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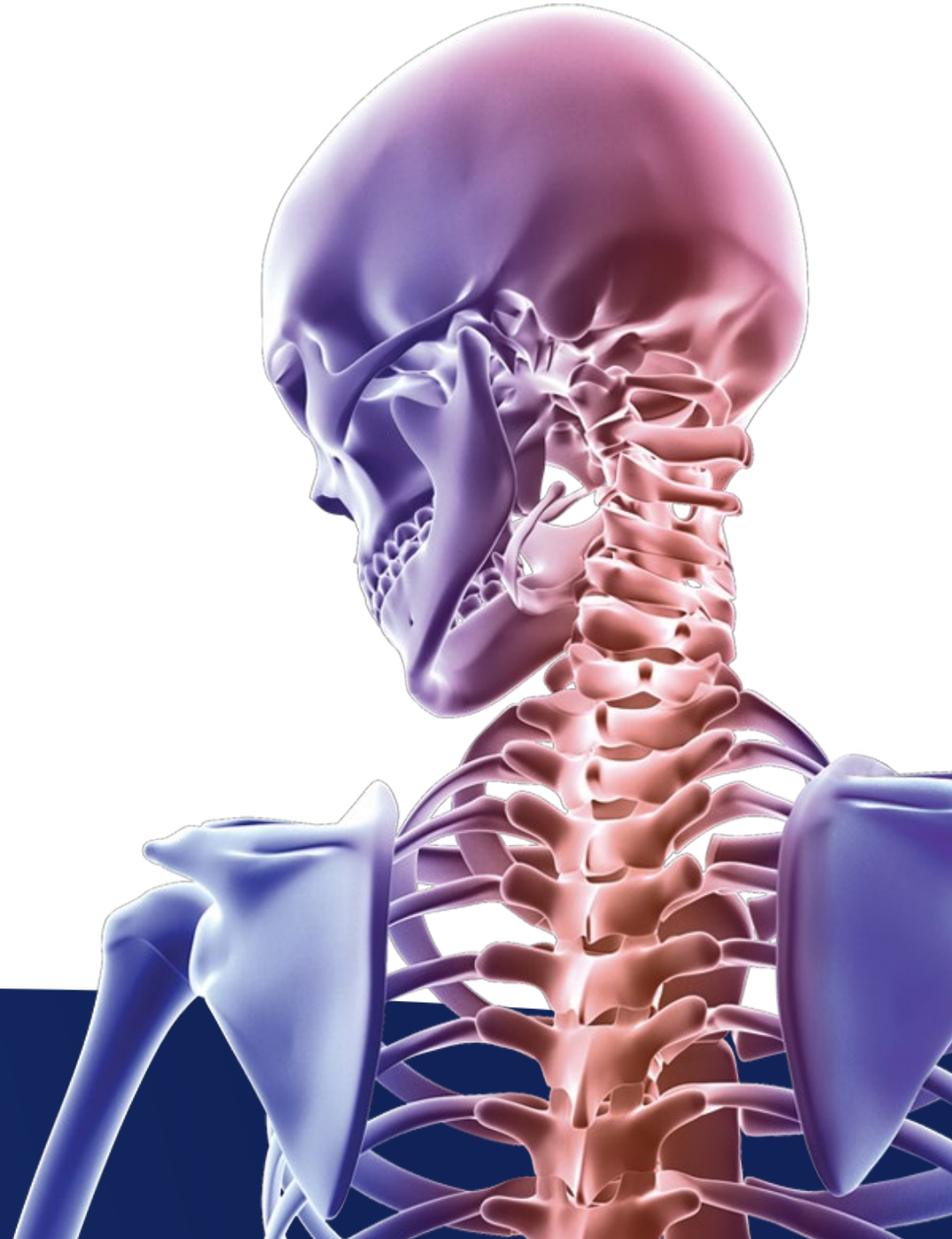

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# AGENDA

*MDR Requirements – Remediation?*

*Equivalence – Medical Devices*

*Significant Change vs. Substantial Change*

*FDA vs. CE Mark*

# MDR Requirements Remediations?


**P**erson **R**esponsible for **R**egulatory **C**ompliance (**PRRC**)

**1. Gap Analysis and Project Planning**
Project Management

**2. Enhanced Clinical Evidence**
Clinical Research
Post-Market Surveillance

**3. Technical Documentation Update**
Product Development
Quality Assurance

**4. UDI Implementation and EUDAMED Registration**
Operations and Manufacturing
IT Systems

**5. Reclassification of Devices**
Product Development

**6. Quality Management System (QMS) Update**
Quality Assurance

**7. Supply Chain and Economic Operators Compliance**
Operations and Manufacturing
Sales and Marketing & Transportation and Logistics

**8. Risk Management and Post-Market Activities Enhancement**
Product Development & Risk Management:
Post-Market Surveillance

**9. Training and Awareness**
All Functions

**10. Notified Body Interaction - Leadership**
Quality Assurance


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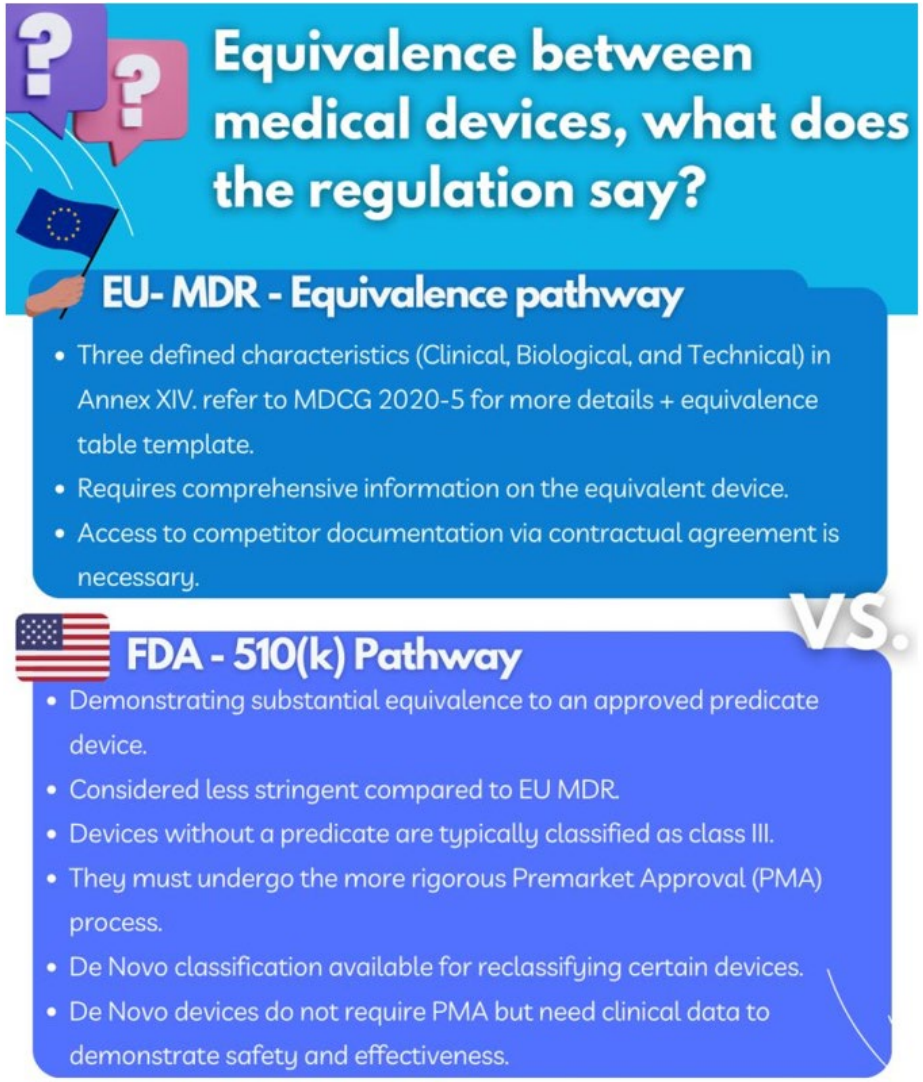
**Equivalence**
**Medical Devices**

EU-MDR – Equivalence Pathway
- **Clinical**, Biological and Technical
- Access to Competitor Documentation

FDA – 510(k) Pathway
- Substantial equivalence – less stringent
- Premarket Approval (PMA)
- De Novo

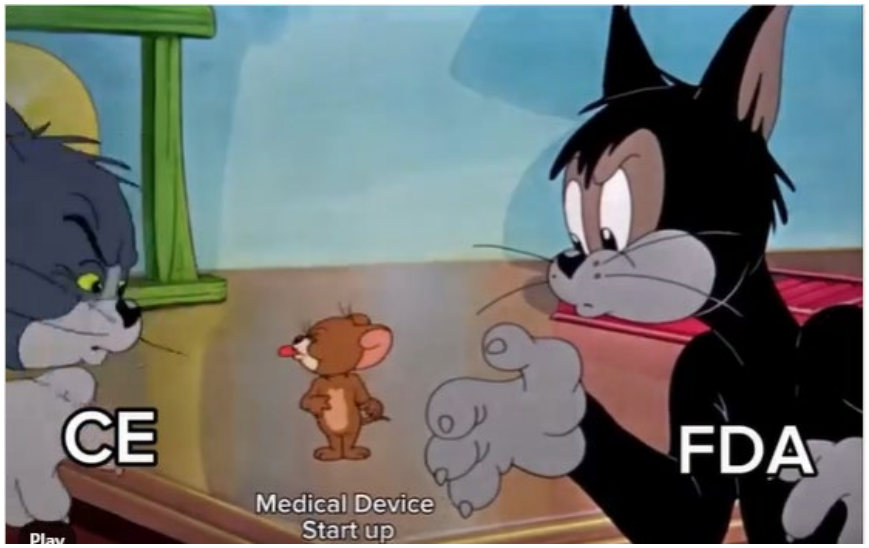


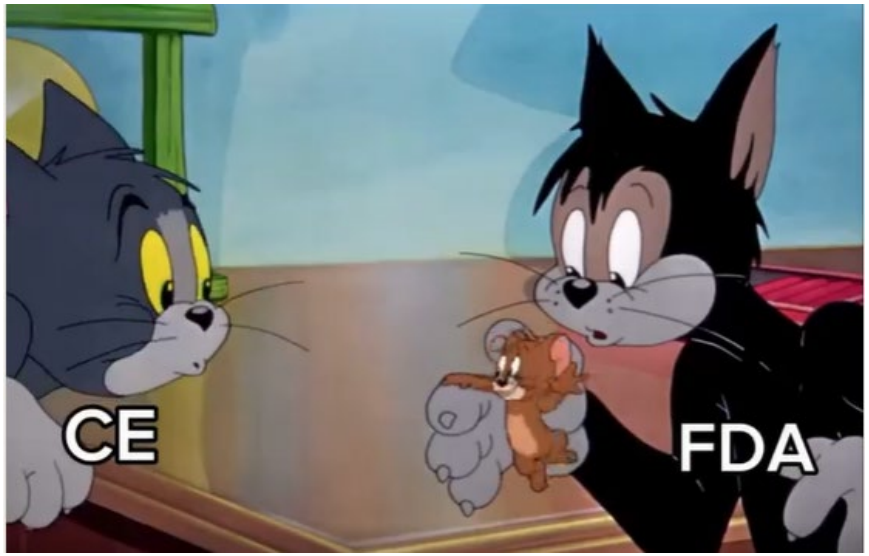
**Significant Change**
**vs.**
**Substantial Change**


Chart A – Intended purpose changes
Chart B – Design changes
Chart C – Software changes
Chart D – Material or substance/ingredient changes
Chart E – Sterilization changes

# FDA vs. CE Mark


Requirements?
Cost?
Time?



*In summary…What is the true impact on industry?*

Legacy devices (Design Controls?)

Clinical (Data Collection?)

Product obsolescence (Time and cost?)

Innovative devices (US?)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# Questions?

# Thank You

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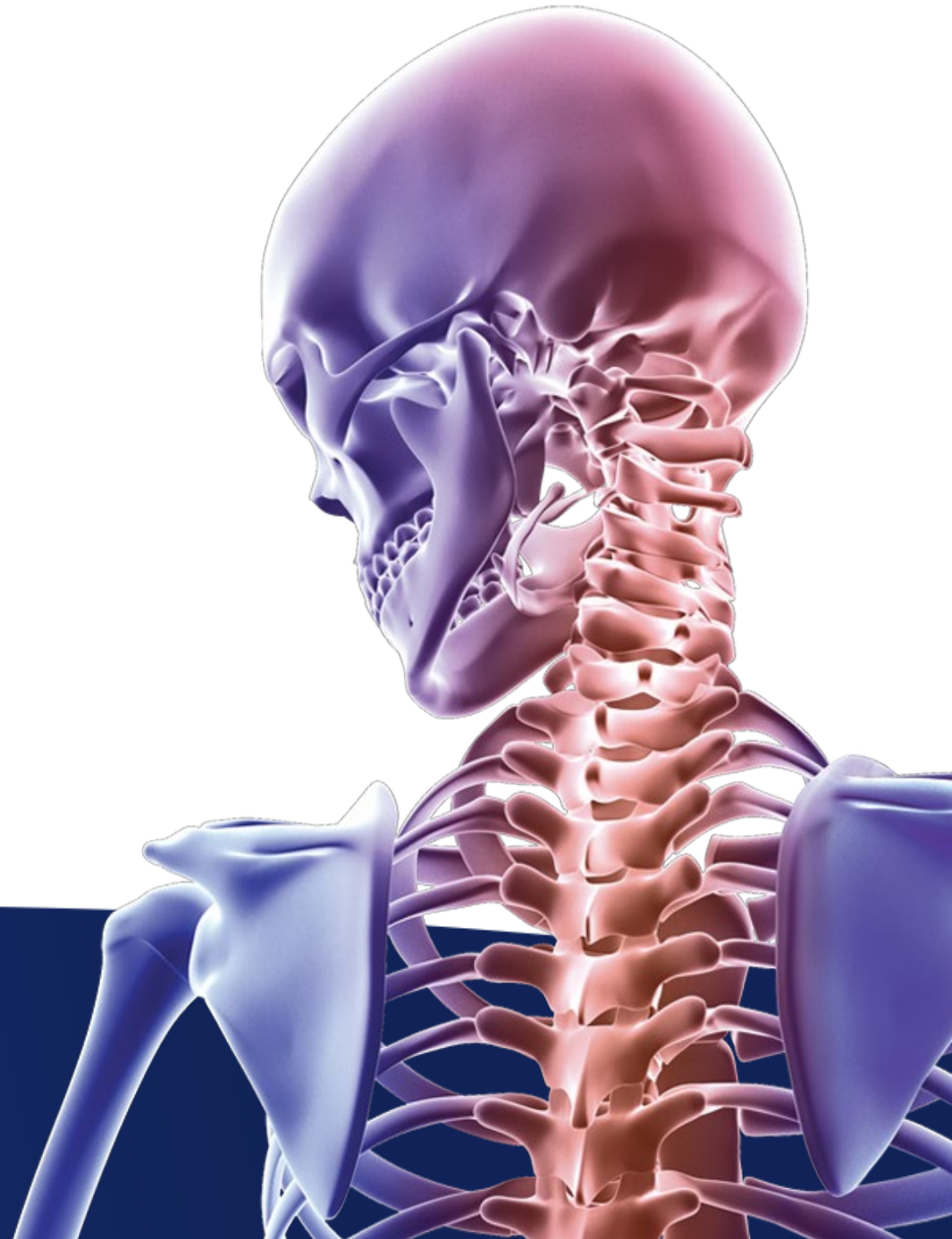

# Conquer the MDR Maze - Challenges and Expectations for Clinical Evidence

Matthias Fink, MD
Orthopedic Surgeon and
Senior Clinical Consultant

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Orthopaedic Surgical Manufacturers Association

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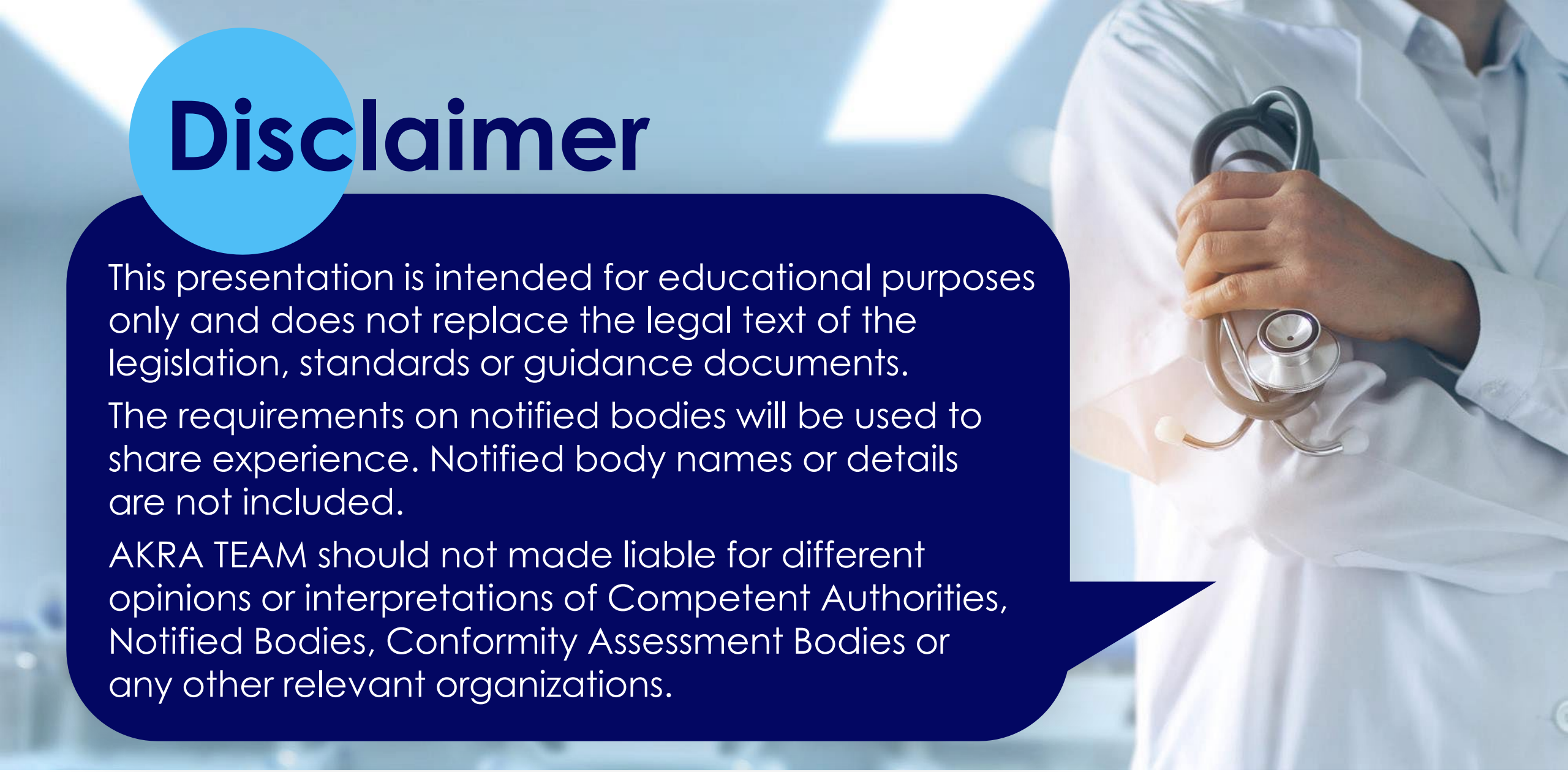
# Disclaimer



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The requirements on notified bodies will be used to share experience. Notified body names or details are not included.

AKRA TEAM should not made liable for different opinions or interpretations of Competent Authorities, Notified Bodies, Conformity Assessment Bodies or any other relevant organizations.

# Should patients be worried?

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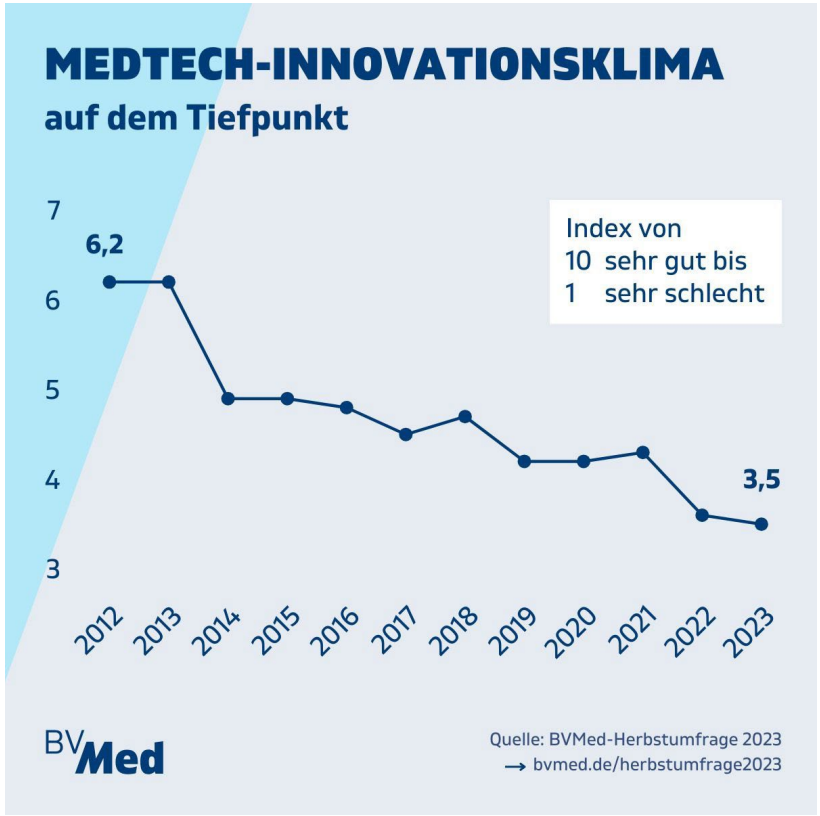
Healthcare & Pharmaceuticals | Medtech | Regulatory

## Insight: Medical device makers drop products as EU law sows chaos

By Maggie Fick

December 18, 2022 10:39 PM PST · Updated a year ago

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## Children will die unless EU acts on medical equipment rules, warns doctor

Stringent new requirements have forced livesaving devices off the market.

ESC European Society of Cardiology

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ESC Press Office

Press releases

## European cardiologists call for urgent action to prevent medical device shortages

07 Dec 2022

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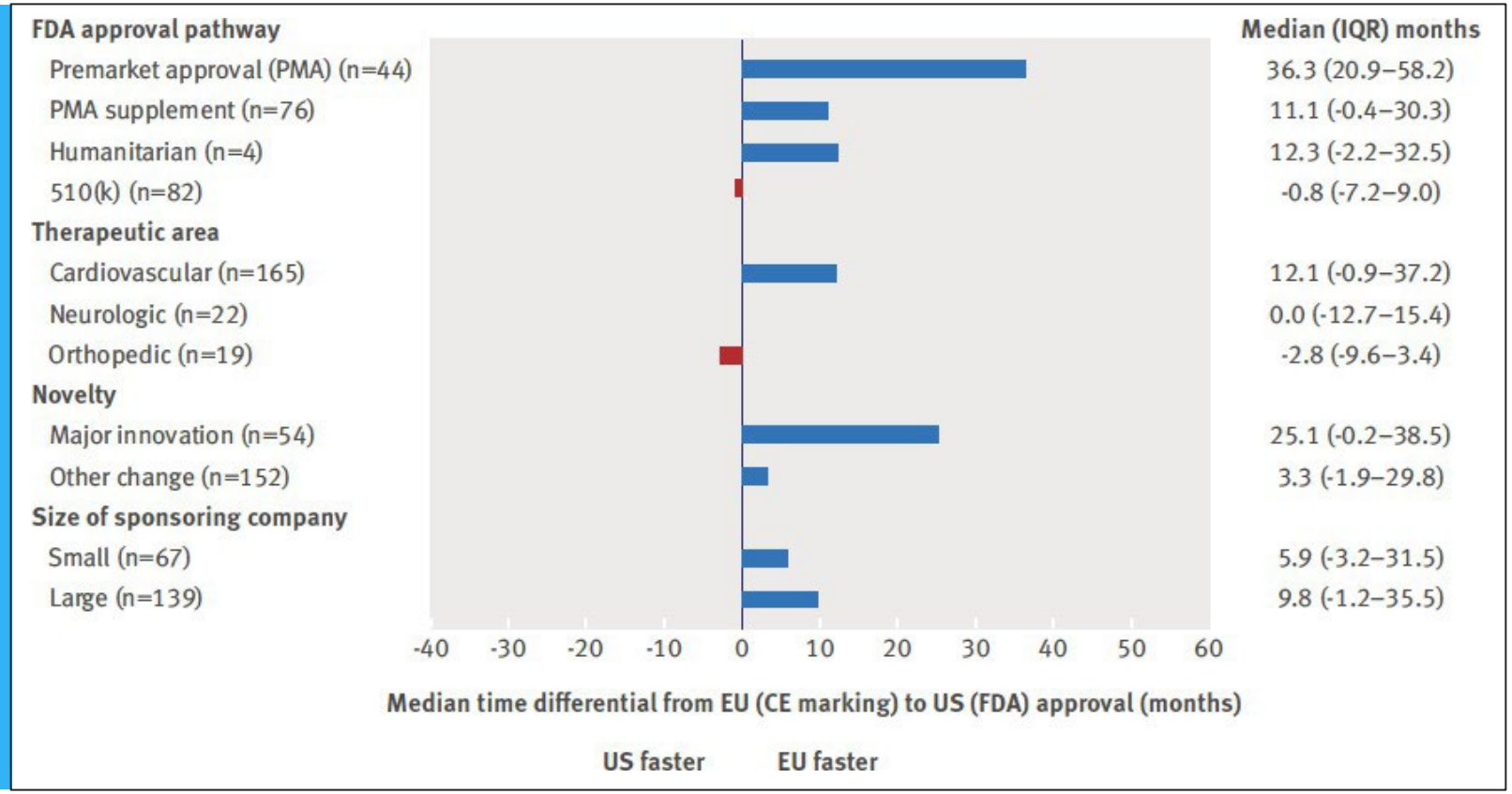
# Approval times for Medical Devices - EU vs. US

Data from 2005 to 2010

- 309 new devices in EU
- 67% EU and US
- 63% EU first




*Hwang et. al, BMJ 2016*

# Initiatives from the Medtech Industry

BVMed Die Stimme der deutschen MedTech-Branche

VDGH Verband der Diagnostica-Industrie

**Summary BVMed and VDGH White Paper on the Future Development of the MDR and IVDR**

In cooperation with Erik Vollebregt – Axon Lawyers

BVMed and VDGH have drafted a white paper that discusses the consequences of the underperforming regulatory system for healthcare, innovation and the position of the CE mark for medical devices and IVDs internationally. The white paper proposes several solutions, grouped by the following categories:

- Measures to supplement the current regulatory system set out under the MDR and IVDR;
- Measures to increase efficiency and implement principles of good administration;
- Reform of the current five-year certification cycle;
- Increased international cooperation and regulatory reliance; and
- Centralisation of responsibility and policy within the regulatory system.

To: European Commission, DG SANTE
Attn.: European Commissioner for Health and Food Safety Stella Kyriakides
Address: Rue de la Loi 200
Postcode – City: 1049 Brussels
Country: Belgium

Brussels, 14 September 2023

**Open Letter: Need for comprehensive structural reform to address healthcare access challenges resulting from the EU regulatory framework for medical technologies**

Dear Commissioner Kyriakides,

✓ **Efficient CE Marking System**

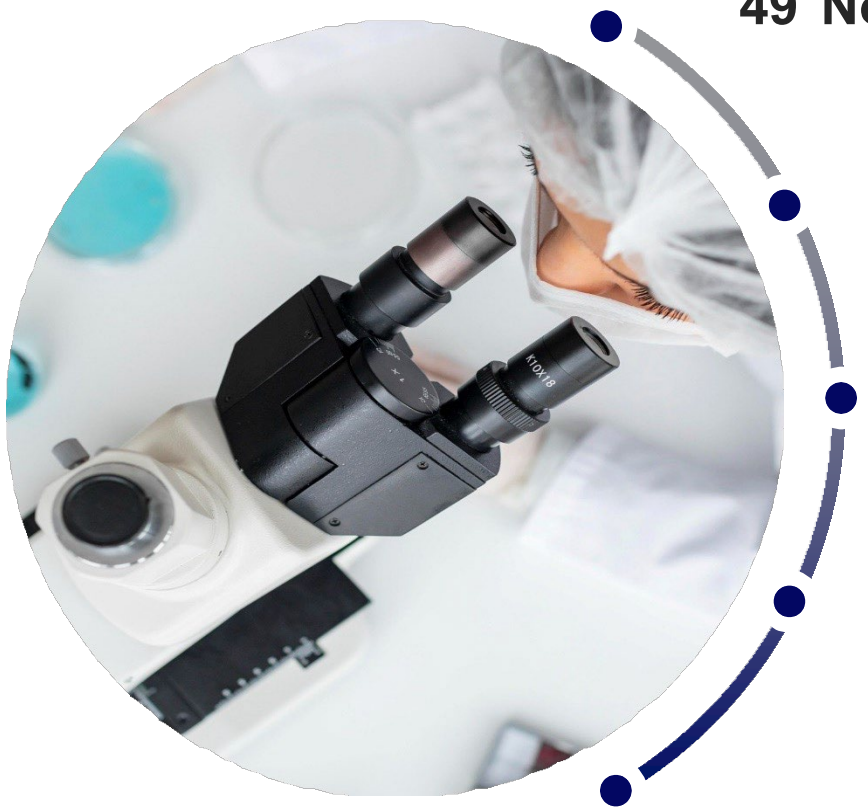
✓ **Support for Innovation**

✓ **Accountable Governance Structure**

# Political measures to ensure a more sustainable future plan

Germany is taking the lead on pushing politically towards a systematic revision of the EU Regulation to keep EU Attractive for Innovative Manufacturers

# Biggest Challenges for Clinical Evidence



**49 Notified Bodies and 27 National Competent Authorities**

**> 100 MDCG Guidance Documents**

**Learning Curve** (NB and Manufacturer)

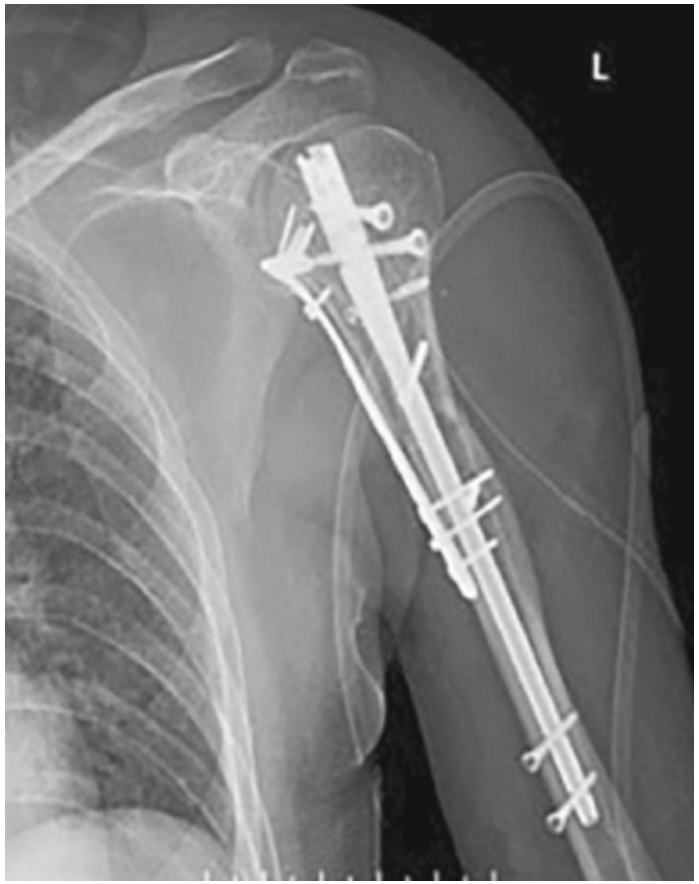
**Insufficient clinical data for legacy devices**

**Expectations on clinical evidence differ between NBs**

# Higher Scrutiny for Class IIb Implantable Devices

*Annex IX; not applicable for devices listed in Art, 61.6(b)*

> 4.4. The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.

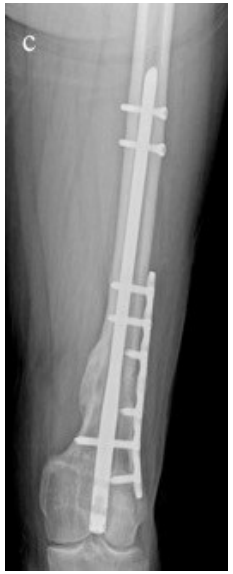



## Additional Challenges:

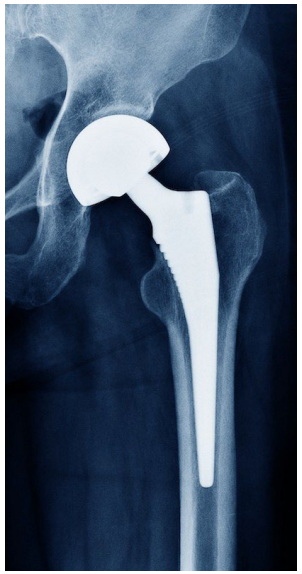
- **Up-classification** of all partial and total joint prostheses and most spinal implants
- Most **IIb legacy orthopedic** devices are now reviewed by a **Clinical Reviewer**
- **Higher focus on the clinical data** compared to assessments under the Directives

# Classification EU vs. US

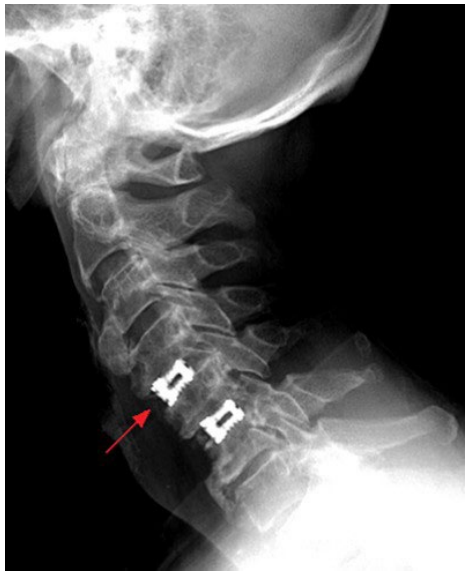
- **US**[1] 35% Class I, 53% Class II, **9% Class III**
- **EU**[2] ~40% Class I, ~21% Class IIa, ~23% Class IIb, **~16% Class III**



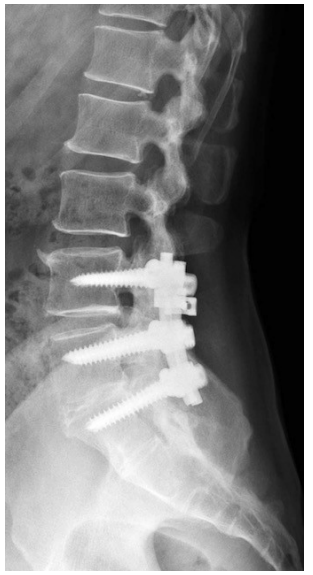
US=EU



US≠EU



US≠EU



US≠EU

- **Approximately 97% of orthopedic medical devices are 510(k) cleared (Dubin et al. 2021)**

[1] *FDA Presentation 2022*
[2] *MedTech Europe Survey Report, published 2022*

# Transferability of Real-World Data

## What needs to be considered

# More Alignment between Notified Bodies?


- **MDCG 2020-13**
- Joint events at regulatory conferences and meetings
- Alignment between Team-NB members on clinical topics
- Mandatory Clinical Evaluation Consultation Procedure

TEAM NB
The European Association for Medical devices of Notified Bodies

osma
Orthopaedic Surgical Manufacturers Association

What is new with clinical data under the MDR? Interactive panel session with Notified Bodies

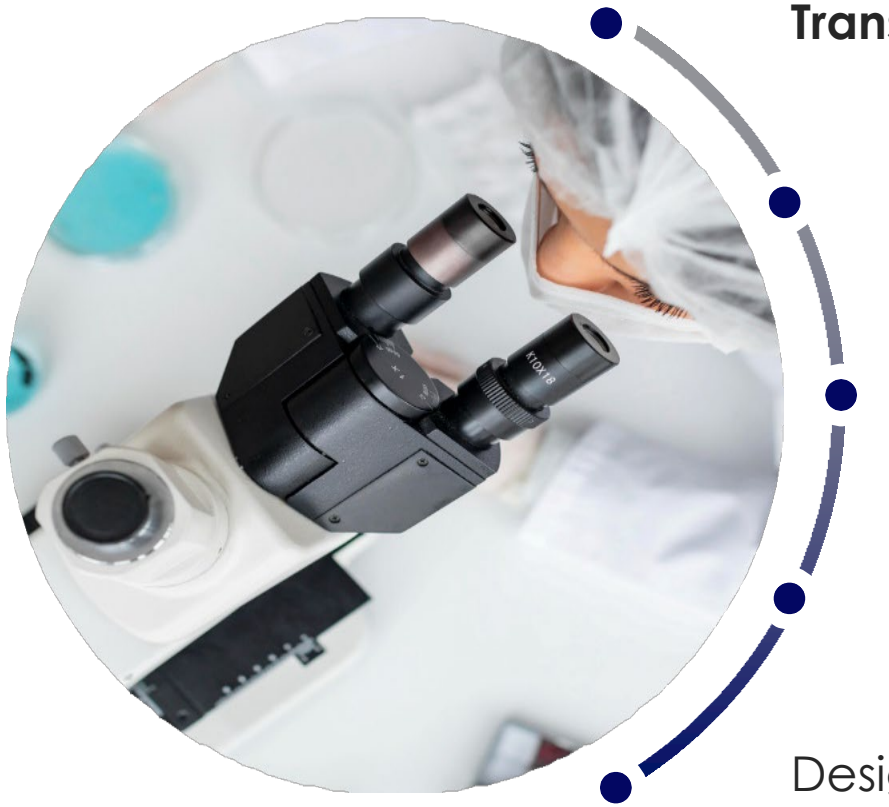
Session Leader: Matthias Fink, MD – Akra Team Inc.
Presenter: Richard G. Holborow – BSI
Presenter: Christoph Ziskoven, MD – TÜV Rheinland LGA Products GmbH
Presenter: Ulrich Nitsche, MD – TÜV SÜD Product Service GmbH

Devices (includes Medical Devices and In Vitro Diagnostics)

# Notable Statements from the Scientific Opinions

## Published Scientific Opinions

https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en



**Transferability of clinical data** between different indications

Could **not follow the benefit-risk conclusion** of the NB

**Quality of the literature search**
EP cited literature not disclosed by manufacturer

**Generic device group still considered SOTA**
(Metal-back Glenoid)

Design and number of patients included in **PMCF studies**

# Questions?

## Contact Us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