Update on EU regulatory developments

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Revision of the EU Medical Devices Legislation

-Background-

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

Proposal for a Regulation on medical devices

Directive 98/79/EC on in vitro diagnostic medical devices

Proposal for a Regulation on in vitro diagnostic medical devices
Revision of the EU Medical Devices Legislation
- State of play -

- European Parliament vote on amendments and negotiation mandates: 22 October 2013

- European Parliament 1st reading vote: 3 April 2014 (tbc)

- Council: discussions on the proposals ongoing

IMDRF International Medical Device Regulators Forum
Thank you for your attention!

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