How to bring AI medical devices to the market

Regulatory Insights

About me

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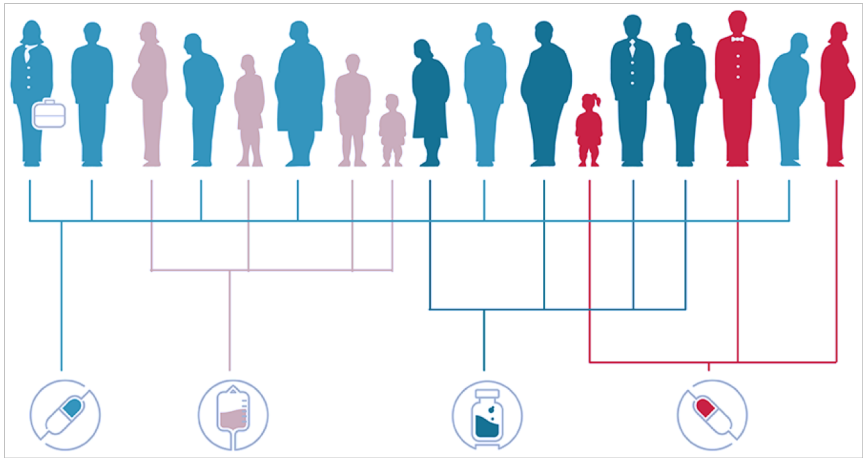

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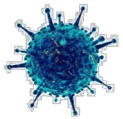
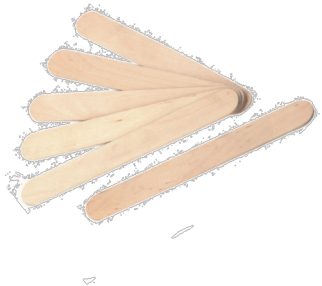
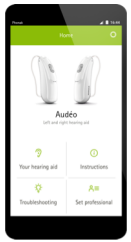
HEAR THE WORLD

Medical Device Types

From an European Regulatory perspective







Class III

Class IIb

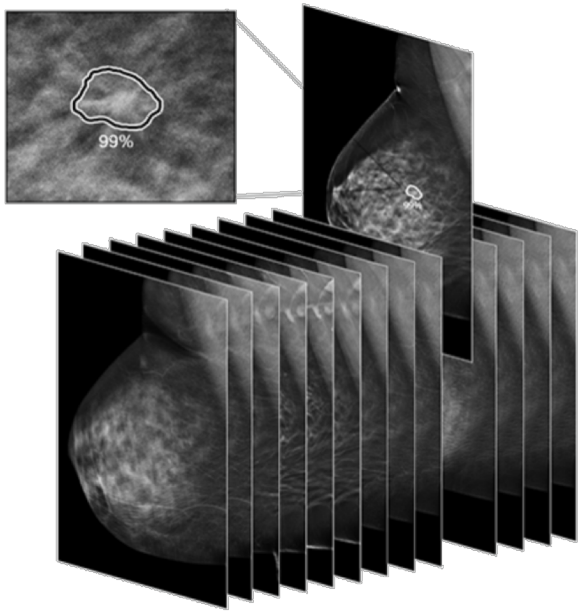
Class IIa

Class I

** Disclaimer: the European regulatory framework has been recently modified. Strictly speaking, there are still 3 types of medical technologies: in vitro diagnostic medical devices, medical devices and active implantable medical devices. The last 2 types, however, are merged into one single category under the Medical Device Regulation (MDR).*

Breast Cancer Detection Algorithm

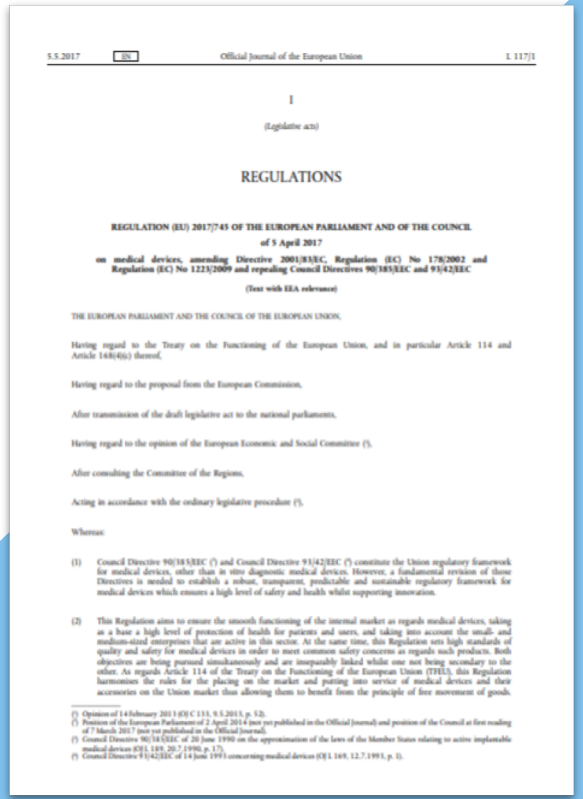
Deep Learning as a Medical Device



Regulatory Authorities

European Medical Device Market

Regulations (EU) 2017/745&746



5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

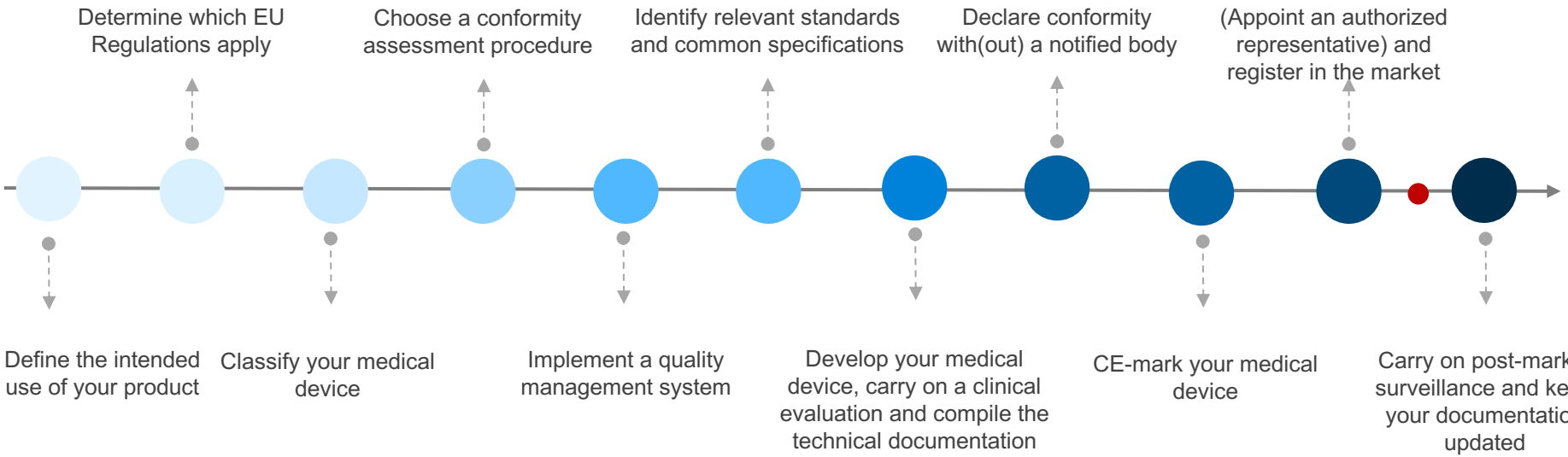
(1) Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

(1) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
(2) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
(3) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
(4) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

In a nutshell

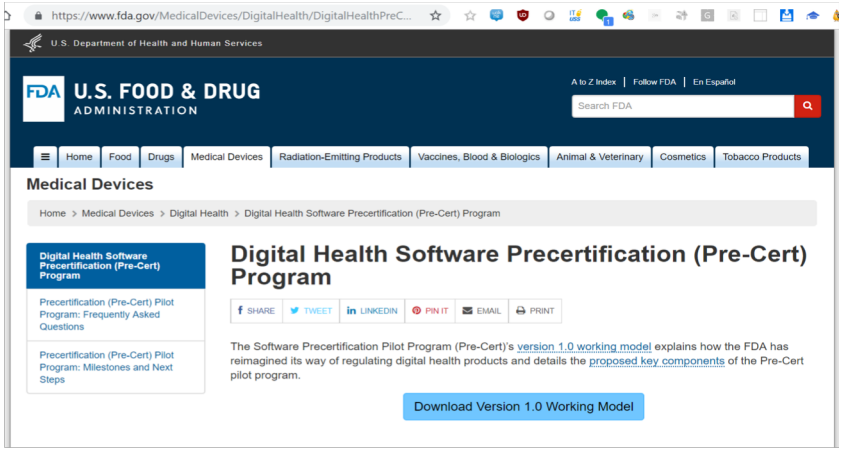
Steps to bring a medical device to the market

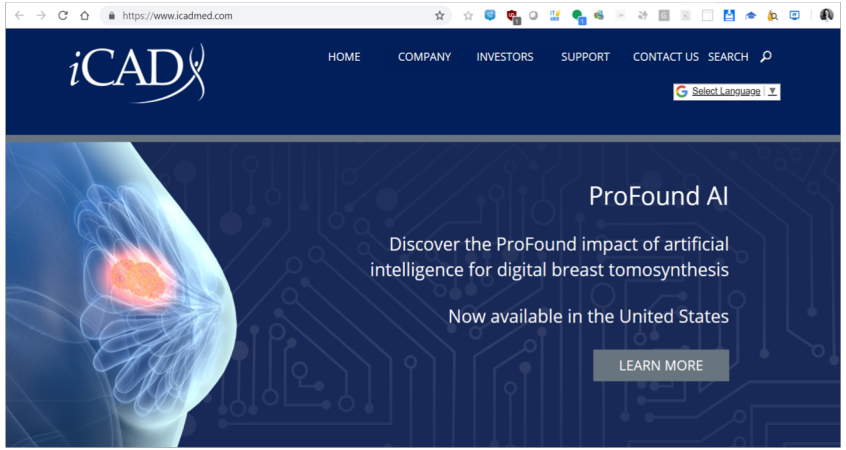


Regulating AI

"AI holds enormous promise for the future of medicine. We're actively developing a new regulatory framework to promote innovation in this space and support the use of AI-based technologies"

FDA Commissioner Scott Gottlieb, MD





Doing now what patients need next

Gloria Macia