MDR – a physician/innovator perspective on accelerated approval processes

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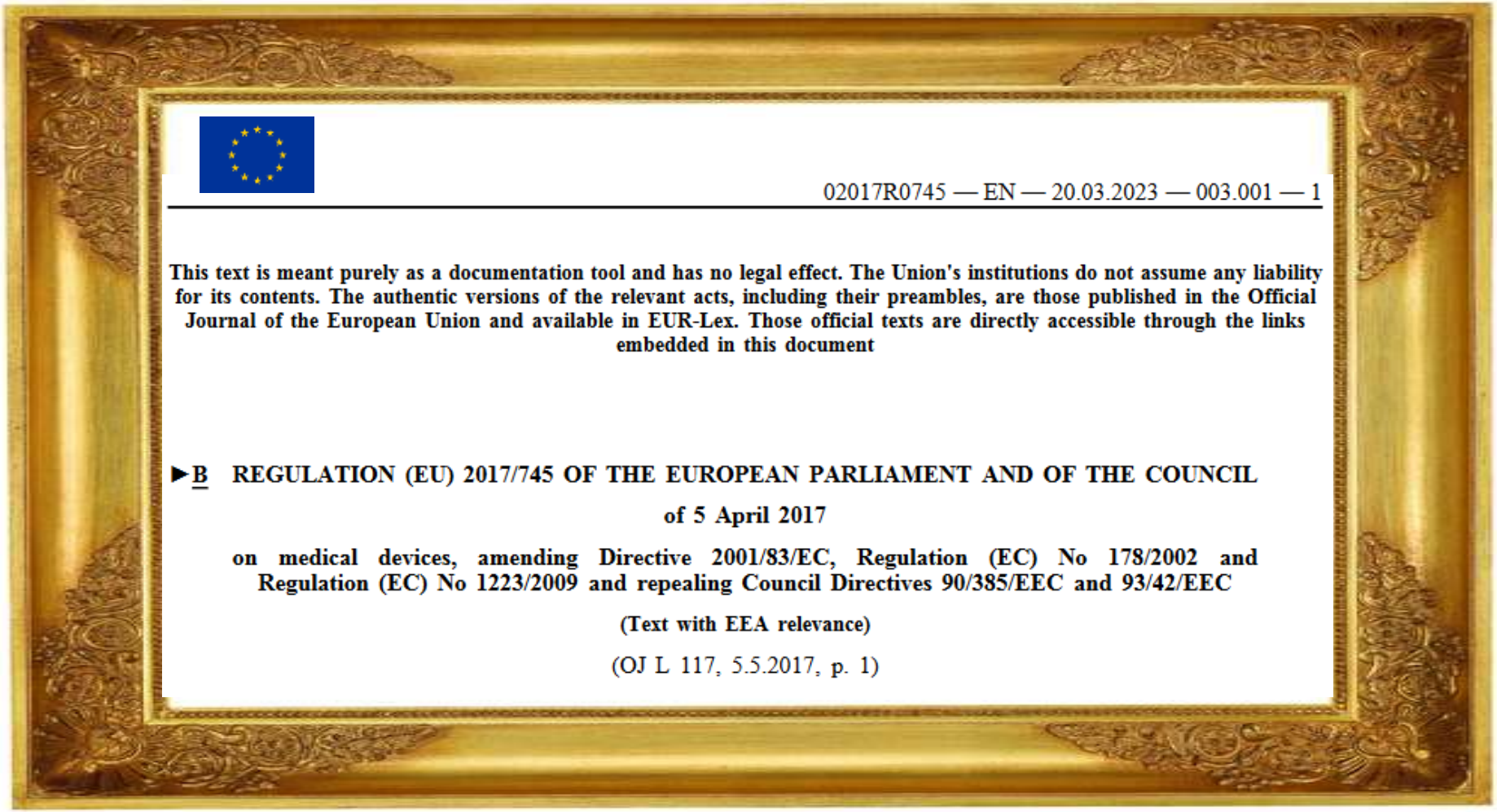
ToDo List

for cardiovascular implants

- **Regulatory rules of notified bodies**
- **Material properties – lifetime management**
- **Bio compatibility**

Medical Device Regulation of EU



▶B 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)

(OJ L 117, 5.5.2017, p. 1)

Medical Device Regulation - EU

02017R0745 — EN — 20.03.2023 — 003.001 — 1

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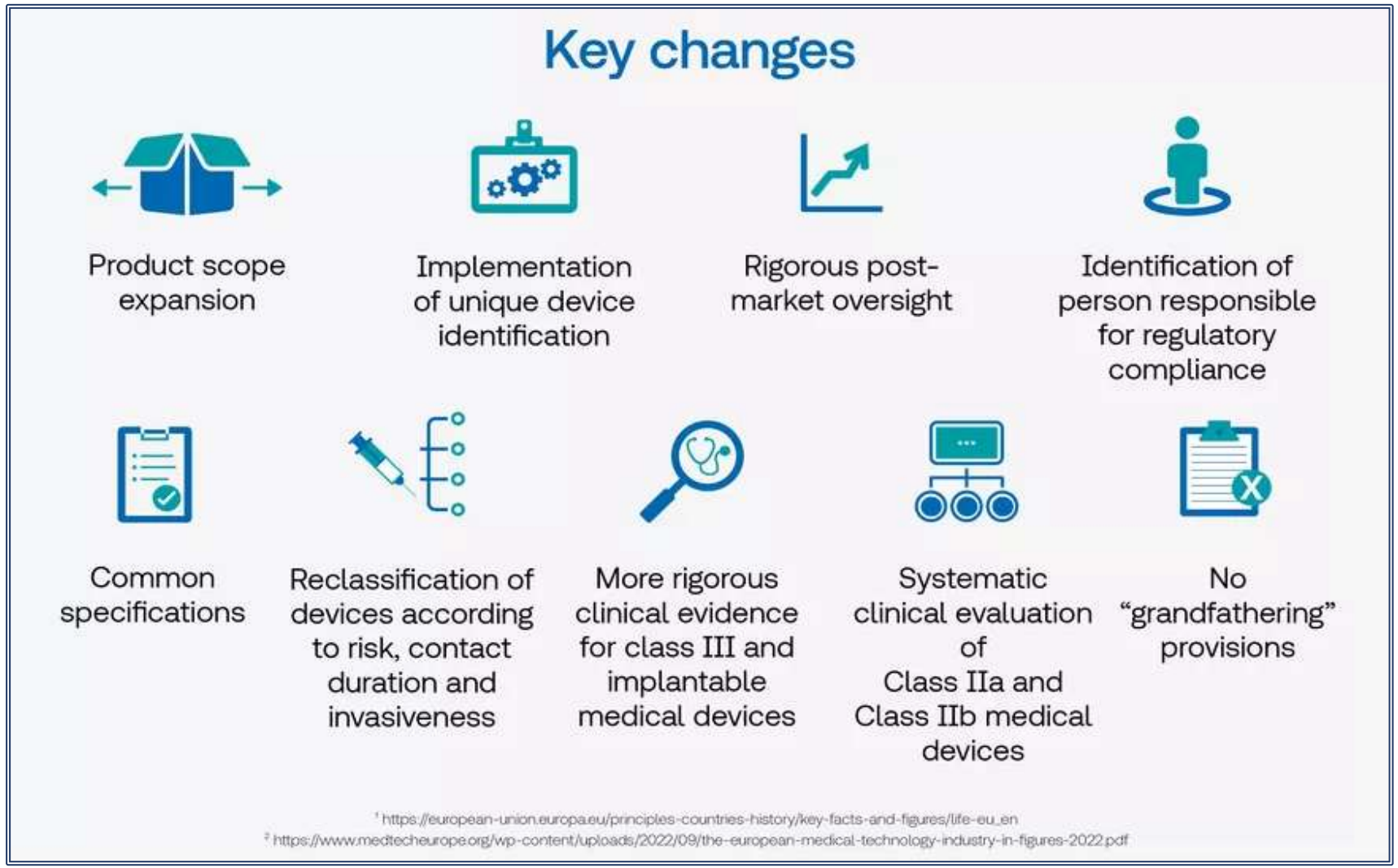
Medical Device Regulation - EU



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https://doi.org/10.1080/17434440.2023.2192868

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PERSPECTIVE

OPEN ACCESS

An accelerated access pathway for innovative high-risk medical devices under the new European Union Medical Devices and health technology assessment regulations? Analysis and recommendations

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ABSTRACT

Introduction: The new European Union (EU) Regulations for medical devices (MDs) and health technology assessment (HTA) are welcome developments that should increase the quality of clinical evidence for MDs and reduce fragmentation in the EU market access process. To fully exploit anticipated benefits, their respective assessment processes should be closely coordinated, particularly for promising, highly innovative MDs. Accelerated approval is worth exploring for certain categories of high-risk MDs to keep the EU regulatory process competitive compared to accelerated MD approval programs elsewhere (e.g. US).

ARTICLE HISTORY
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KEYWORDS
Accelerated approval; high-risk implantable medical devices; clinical evidence; European union; medical

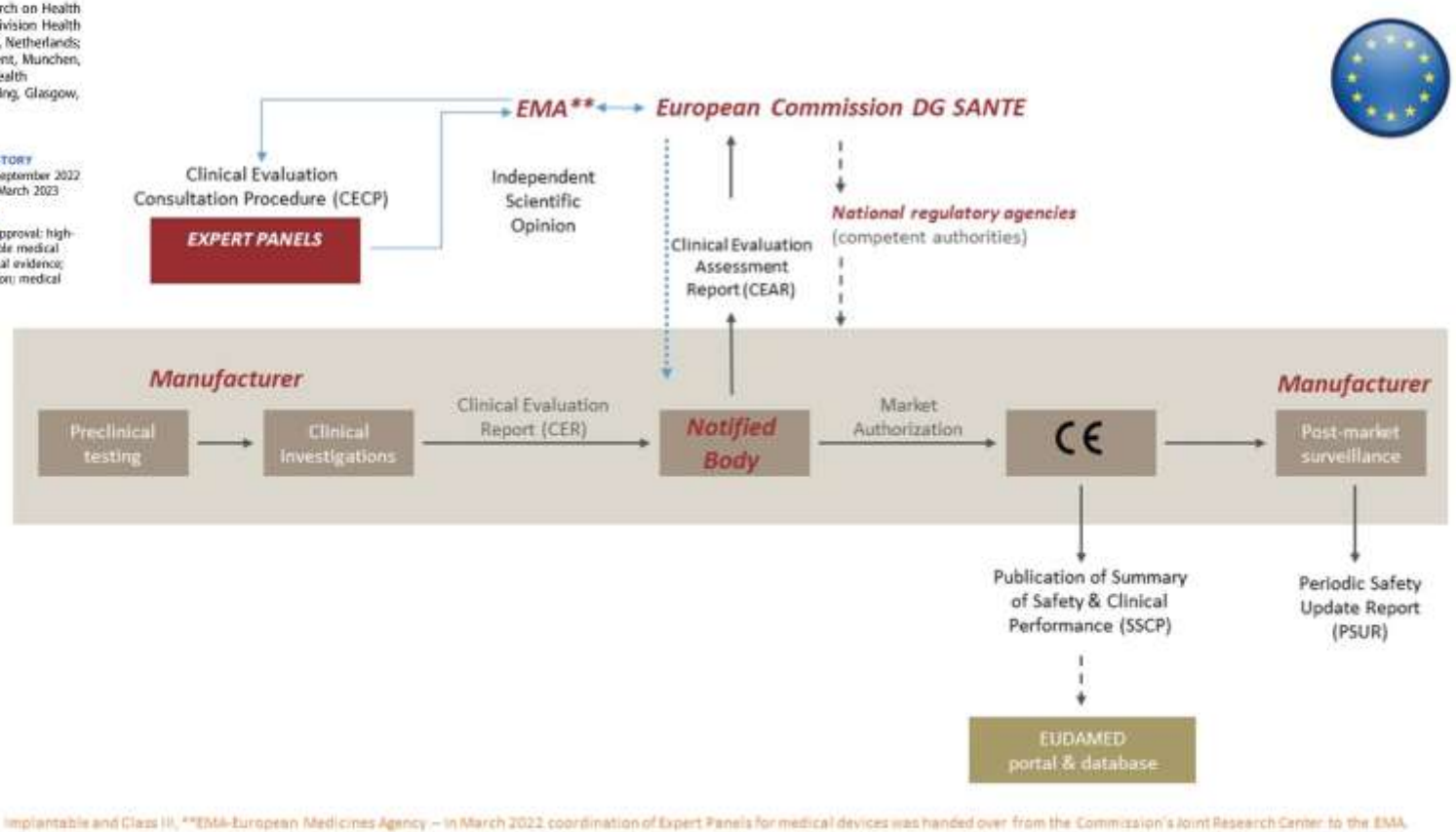
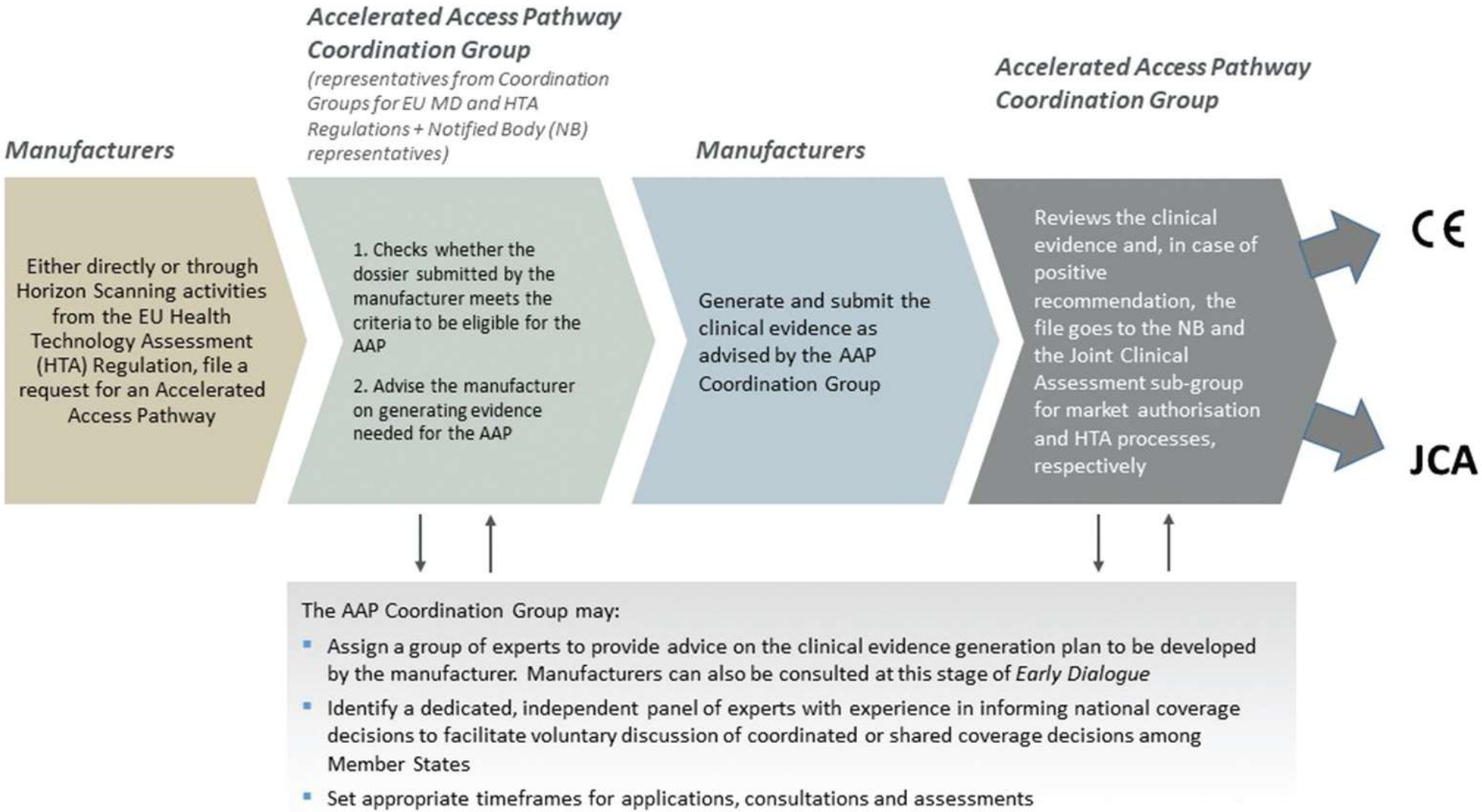


Figure 1. The current premarket development and regulatory approval pathway for high-risk* medical devices in the European Union. Reprinted (adapted) with permission from Fraser AG, Byrne RA, Kautzner J, et al. Implementing the new European Regulations on medical devices - clinical responsibilities for evidence based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology. Eur Heart J. 2020;41:2589–2596.



2. A proposal for an Accelerated Access Pathway (AAP) in the European Union (EU) for innovative high-risk implantable medical devices (MDs).

- The MD is intended for the prevention, diagnosis or treatment or rehabilitation of a life threatening or seriously debilitating disease or condition.
- The MD addresses an unmet medical need, or a minimum yet high quality set of evidence is provided that pursuit of a standard pathway would preclude patients from access to needed treatment while guaranteeing patient safety.
- There are no predicates and the device represents a novel or highly promising technology for patients in immediate need, that is, based on preliminary evidence, it offers a significant added clinical and/or non-clinical (survival benefits, significant health-related quality of life gained, reduction of morbidity, safety, care pathway efficiency,

JAMA. 2022 Aug 9; 328(6): 580–582.
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https://doi.org/10.1001/jama.2022.10041

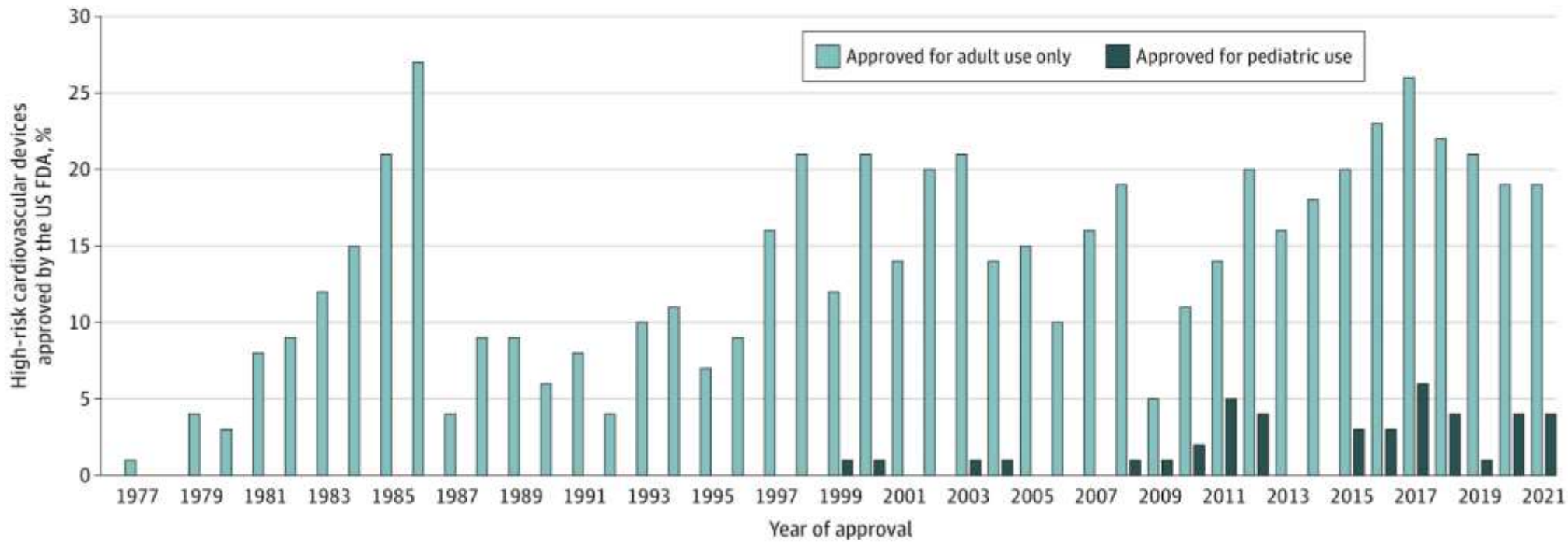
PMCID: PMC9364120
PMID: 35943478

US Food and Drug Administration Approval of High-risk Cardiovascular Devices for Use in Children and Adolescents, 1977-2021

Susmitha Wunnava, PhD,[1] Timothy A. Miller, PhD,[2] Claire Narang, BS,[2] Meena Nathan, MD, MPH,[3] and Florence T. Bourgeois, MD, MPH[2,4]

Published online 2022 Aug 9. doi: 10.1001/jama.2022.10041

Figure.



REGULATORY UPDATE

Swiss Regulators Set to Recognize US FDA-cleared or Approved Medical Devices

New laws to allow manufacturers to leverage their FDA registrations for Swiss market access

Contact us

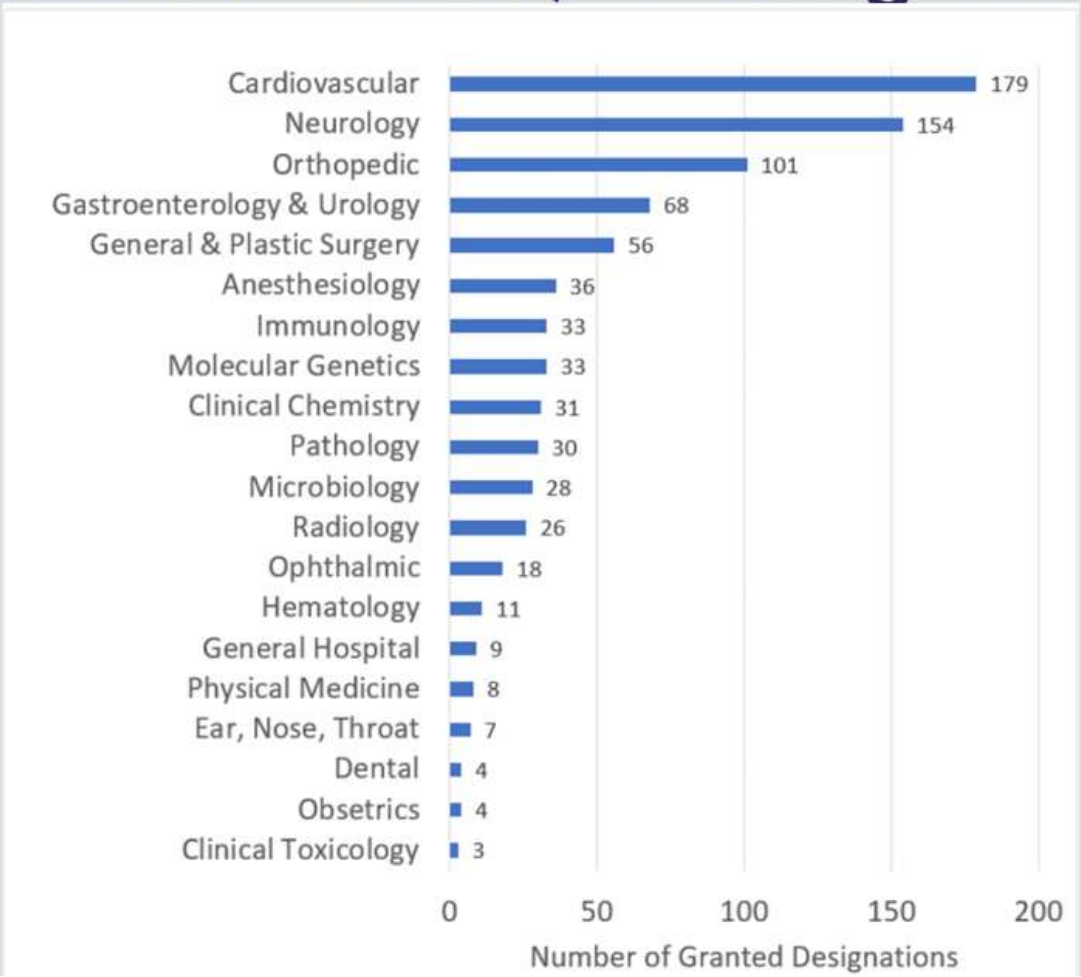
November 30, 2022

By Annette Van Raamsdonk

Swiss legislators have authorized adoption of new laws to recognize medical devices and in vitro diagnostic (IVD) devices that have received US Food and Drug Administration (FDA) clearance or approval as well as devices with EU CE marking. In doing so, Switzerland joins many other countries that have expanded medical device regulatory authorizations in order to protect continuity of healthcare for their populations.

According to the Swiss Medical Technology Association (Swiss Medtech), adoption of these new laws will create more leeway in terms of procuring medical devices and IVDs for Swiss patients. Manufacturers, Notified Bodies and healthcare providers have noted increasing challenges as the European Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) take effect. Lack of Notified Body capacity to take on new clients as well as stricter regulatory requirements are expected to lead to shortages of devices with valid CE certification.

Number of Granted Breakthrough Designation Requests by Clinical Panel (**through June 30, 2023)



As of June 30, 2023, 81 Breakthrough Devices have received marketing authorization.

- 77 in CDRH, 4 in CBER
- List of all devices available here: Breakthrough Devices Program | FDA

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
RENALYTIX AI, INC.	KIDNEYINTELX.DKD	DEN200052	06/29/2023
ABBOTT MEDICAL	AVEIR DR LEADLESS SYSTEM	P150035/S003	06/29/2023
AVITA MEDICAL AMERICAS, LLC.	RECELL AUTOLOGOUS CELL HARVESTING DEVICE	BP220799	06/16/2023
PREMIA SPINE, LTD.	TOPS SYSTEM	P220002	06/15/2023
AVITA MEDICAL AMERICAS, LLC	RECELL AUTOLOGOUS CELL HARVESTING DEVICE	BP170122/S502	06/07/2023
ENDOLOGIX, LLC.	DETOUR SYSTEM	P220021	06/07/2023
CERIBELL, INC.	CERIBELL STATUS EPILEPTICUS MONITOR	K223504	05/23/2023
BRAHMS GMBH, PART OF THERMO FISHER SCIENTIFIC	B·R·A·H·M·S SFLT-1/ PLGF KRYPTOR TEST SYSTEM	DEN220027	05/18/2023
SWING THERAPEUTICS, INC.	STANZA	DEN220083	05/09/2023
W. L. GORE & ASSOCIATES, INC.	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	P210032/S007	05/02/2023
NOCTRIX HEALTH, INC.	NTX100 TONIC MOTOR ACTIVATION (NTX100 TOMAC) SYSTEM	DEN220059	04/17/2023
MOXIMED, INC.	MISHA KNEE SYSTEM	DEN220033	04/10/2023
MASIMO CORPORATION	MASIMO SAFETYNET OPIOID SYSTEM	DEN200011	03/31/2023
BIORETEC, LTD.	REMEOS SCREW LAG SOLID	DEN220030	03/29/2023
REWALK ROBOTICS, LTD.	REWALK P6.0	K221696	03/02/2023
ABBOTT LABORATORIES	TBI	K223602	03/02/2023
REFLEXION MEDICAL, INC.	REFLEXION MEDICAL RADIOTHERAPY SYSTEM (RMRS)	DEN220014	02/01/2023

Pathways for Innovative Medical Devices

Country/Jurisdiction	Program/Pathway name	Responsible entity	Details
Australia	Priority Review designation	TGA	Priority application guidelines and application forms are available.
Canada	Pathway for advanced therapeutic products	Health Canada	Consultation period closed on March, 2023. Innovation information meetings take place.
China	Innovation Green Pathway	NMPA	Applicant's ownership of legal patent rights of the product's core technology in China.
European Union (EU)	Expert Panels	Experts appointed by the European Commission	Several opinions have been provided and are available here.
Japan	Fast Track Review Process	PMDA	Fast-track review and conditional fast-track review pathways.
United Kingdom (UK)	Innovative Devices Access Pathway (IDAP)	MHRA, NICE and other partners	Launched September 2023.
United States of America (USA)	Breakthrough Devices Program	U.S. FDA	As of June 30, 2023, 81 Breakthrough Devices received marketing authorization.

FDA Approves TriClip TEER Device for Tricuspid Repair

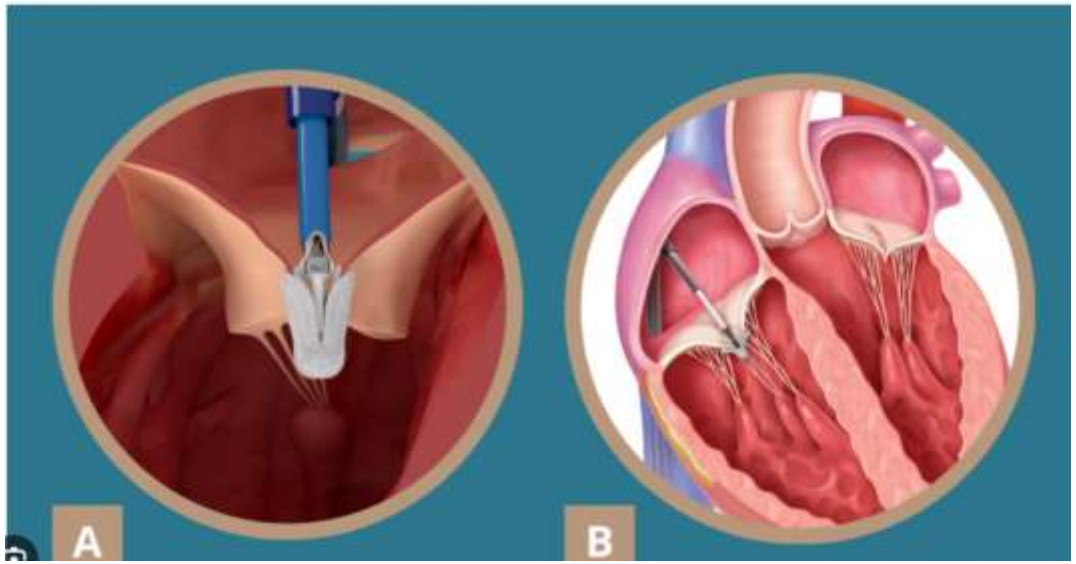
(UPDATED) The approval was based on positive data from the TRILUMINATE pivotal trial, which included a highly symptomatic population.

by L.A. McKeown | APRIL 02, 2024

The US Food and Drug Administration has approved the TriClip device for transcatheter edge-to-edge repair (TEER) in patients with tricuspid regurgitation (TR) who are not candidates for surgery, the manufacturer Abbott announced today.

In February, the FDA's Circulatory System Devices Panel voted 12-2 in favor of TriClip's efficacy, and 14-0 on its safety. The approval is based on strong data from the TRILUMINATE pivotal trial showing that compared with those on medical therapy alone, TriClip patients had a more favorable primary composite outcome (all-cause death or tricuspid valve surgery, hospitalization for heart failure, and improvement in quality of life) after 1 year.

TRILUMINATE patients had symptomatic severe TR and were deemed to have at least an intermediate risk for mortality with tricuspid valve surgery.



U.S. FOOD & DRUG ADMINISTRATION

Medical Devices / Products and Medical Procedures / Device Approvals and Clearances / Recently Approved Devices / Edwards EVOQUE Tricuspid Valve Replacement System – P230013

Edwards EVOQUE Tricuspid Valve Replacement System – P230013

Recently Approved Devices

2024 Device Approvals

2023 Device Approvals

2022 Device Approvals

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Edwards EVOQUE Tricuspid Valve Replacement System
PMA Applicant: Edwards Lifesciences LLC
Address: One Edwards Way, Irvine, CA 92614
Approval Date: February 01, 2024

Content current as of: 02/26/2024

Regulated Product(s)
Medical Devices
Radiation-Emitting Products
Cardiovascular

MDR in EU
Chance, Quality and Risks in structural and congenital interventions – FDA BT/EMA MDR alignments?

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Herz ■ Klappen ■ Bewegen ■ Leben ■

Thank you!

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