IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

China's Medical Device Regulatory Progress

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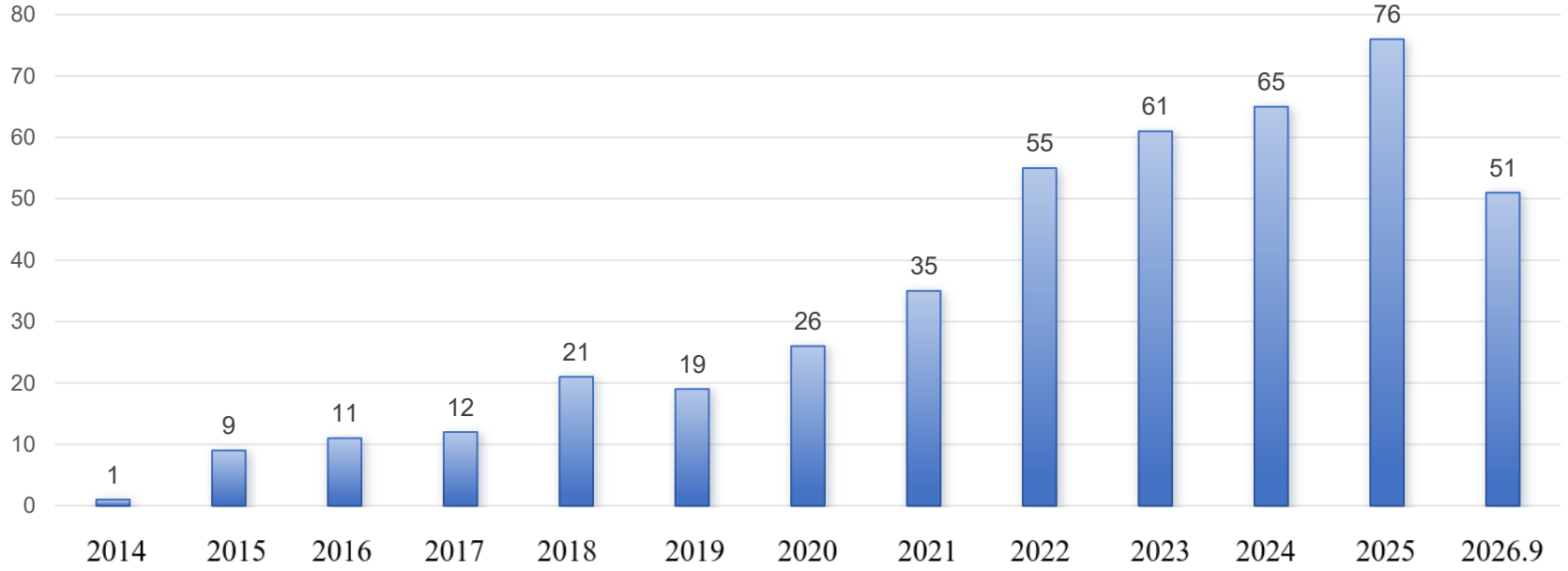
Agenda

1. Recent Measures to Encourage Medical Device Innovation
2. "Spring Rain Action" for Clinical Innovation Translation
3. Progress in Brain-Computer Interface (BCI) Medical Devices
4. Implementation of UDI and Classification Adjustment
5. Progress in Medical Device Registration Review Guidelines and International Coordination

1.Innovative Medical Devices Approved in China

Steady growth year by year — 76 devices approved in 2025



1.Recent Measures to Encourage Medical Device Innovation

01. **Clinical Trial Protocol Pre-review:** In March 2026, CMDE issued a notice to provide early scientific guidance during product development, enhancing R&D efficiency and scientific rigor.
02. **Establishing Innovation Cooperation Platforms:** Three cross-cutting platforms for artificial intelligence, biomaterials, and high-end equipment have been established. An IVD innovation platform is under construction to facilitate industry-academia-research integration and technological collaboration.
03. **Co-regulation of Companion Diagnostics:** CMDE and CDE jointly issued a consultation draft to standardize the synchronous development of anti-tumor drugs and their companion diagnostics, strengthening treatment linkage and ensuring precise matching of diagnosis and treatment.

Note: CMDE = Center for Medical Device Evaluation; CDE = Center for Drug Evaluation

2."Spring Rain Action": Transforming Clinical Innovation

Nationwide 3-Year Initiative | NMPA, March 2026 | Clinical value-driven, medicine-engineering integration

1

Collect & Screen

Provincial authorities collect projects from hospitals and screen promising candidates.

2

Match & Connect

Projects paired with manufacturers to build medicine-engineering teams.

3

Guide & Cultivate

Hands-on guidance from concept to prototype, authorities involved throughout.

4

Transform & Launch

CMDE evaluates finalized products. Qualified ones enter pre-submission channel.

3.Regulatory Progress for Brain-Computer Interface (BCI) Devices

Regulatory Science & Pre-review Guidance

Established a dedicated research team to track global BCI tech trends. Provided pre-review guidance for over 10 invasive BCI products, offering professional support to accelerate compliant R&D and innovation.

Classification & Nomenclature Standards

Clarified review responsibilities between national and provincial authorities. Released official guidelines for BCI classification and naming to standardize terminology, preventing confusion and ensuring regulatory clarity.

Technical Standards & Evaluation

Developed tailored clinical evaluation pathways for safety & efficacy assessment. Promoted national and industry standards to build a robust technical foundation, ensuring product quality.

3.Milestone: First Invasive BCI Product Approved

Invasive BCI Hand motor function compensation System

Helping spinal cord injury patients regain hand movement.

Post-market, strict monitoring and follow-up will be continuously carried out to dynamically assess product safety and effectiveness, comprehensively safeguarding patient rights and interests.

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NEWS | 16 March 2026

China approves brain chip to treat paralysis — a world first

Chip allows people with paralysis to control a soft robotic hand.

By Rachel Fieldhouse & Xiaoying You

Save article

China has approved a brain implant for people with severe paralysis to help restore their hand movements. The brain–computer interface (BCI) is the first in the world to be available for use outside clinical trials.

4.Implementation of UDI and Classification Adjustment

Announcement No. 15 (Mar 2026)

UDI for Special Circumstances: Clarified UDI requirements for certain medical devices, addressing special scenarios like custom-made devices.

Announcement No. 21 (Mar 2026)

UDI for Subsequent Entities: Jointly issued by NMPA, NHC and NHSA, clarifying requirements and timelines for implementation.

Announcement No. 52 (Jun 2026)

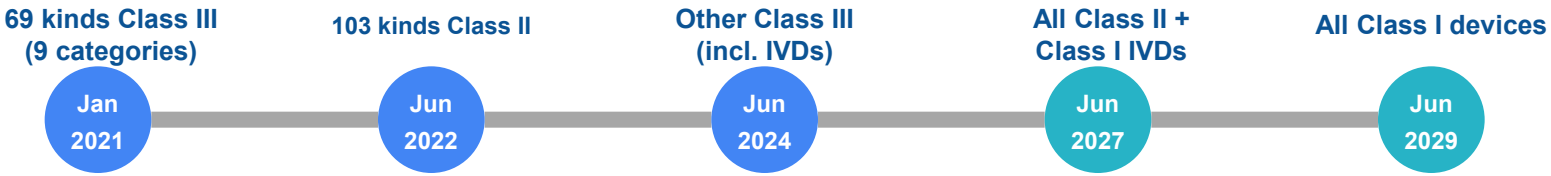
Classification Adjustment Requirements: Clarified practical rules for classification adjustment, for example, transition period management.

Announcement No. 53 (Jun 2026)

Dynamic Adjustment Procedures: Clarified transition principles, step-by-step requirements and agency responsibilities

NHC=National Health Commission；NHSA = National Healthcare Security Administration.

4.UDI Implementation Timeline & Standards



Issuing UDI-Related Standards

7 UDI industry standards published — covering terminology, requirements, creation/placement, and form/content.

Promoting Work Implementation

Established a UDI standardization working group to provide continuous technical guidance and support. Multiple training sessions organized for industry and regulators.

5.Progress in Registration Review Guidelines and International Coordination

2026 Annual Work Progress

• Officially released 75 registration review guidelines.
• 130 draft guidelines are open for public consultation.
• Covering AI medical devices, radiofrequency ablation, dental materials, IVD reagents, etc.

Coordination & Practice with IMDRF

• Actively participated in IMDRF working group activities.
• 97% of IMDRF guidelines have been fully/partially adopted in China.
• Deepen global cooperation to promote regulatory harmonization and reliance.

Thank You!