

SCOPE STATEMENT



Meddevicetracker covers the development progress of medical devices and select diagnostics from research through commercialization. Coverage begins in 2007 and is primarily focused on the US, EU and Japanese markets. Development is tracked through publicly available sources including but not limited to company-issued press releases, SEC filings, medical conferences and journals, clinical trial registries and regulatory documents.

Products

Meddevicetracker covers medical devices and select diagnostics intended for human use.

Inclusions:

For the specific disease/therapeutic areas listed below:

- Class II/III devices (based on US FDA classifications)

For all diseases/therapeutic areas:

- Companion and complementary diagnostics
- Drug-delivery technologies
- Neuromodulation

Exclusions:

- Class I devices (based on US FDA classifications)
- Dental products
- Diagnostics (except companion & complementary)
- Software
- Machines (including imaging & radiation)
- Stand-alone syringes, safety syringes and needles
- Academic or research-use only

Disease/Therapeutic Areas

Meddevicetracker currently covers the following disease areas for which the above inclusion criteria are met:

Autoimmune/Immunology

- Wound Healing

Cardiovascular

- Acute Coronary Syndrome
- Aortic Aneurysm
- Atrial Septal Defect
- Cardiac Arrest/Resuscitation
- Cardiac Surgery
- Congestive Heart Failure & Cardiomyopathies
- Coronary Artery Bypass Graft
- Coronary Artery Disease
- Dysrhythmia
- Hypertension (Systemic)
- Patent Foramen Ovale
- Peripheral Arterial Disease
- Pulmonary Arterial Hypertension

Hematology

- Embolic Stroke Prevention
- Hemostasis
- Venous Thromboembolism

Metabolic/Endocrinology

- Diabetes Mellitus, Type I & II
- Obesity

Neurology

- Pain

Obstetrics/Gynecology

- Contraception
- Female Infertility

Orthopedics

- Bone Fractures & Mechanical Defects
- Cartilage & Joint Repair
- Disc & Spine Repair
- Orthopedic Disorder
- Soft Tissue Repair

Oncology

- Acute Myelogenous Leukemia
- Bladder
- Brain
- Breast
- Cervical
- Chronic Lymphocytic Leukemia
- Colorectal
- Diffuse Large B-Cell Lymphoma
- Esophageal
- Gastric
- Head and Neck
- Hepatocellular (Liver)
- Melanoma
- Multiple Myeloma
- Non-Hodgkin's Lymphoma
- Non-Small Cell Lung Cancer
- Ovarian
- Pancreatic
- Prostate
- Renal
- Small Cell Lung Cancer
- Thyroid
- Uterine (Endometrial)



Development Statuses

Meddevicetracker covers industry-led development of products from research through commercialization. Primary coverage is focused on the US, EU and Japanese markets. Should a product also be developed in markets outside these core areas, coverage may be provided, however, it is not comprehensive. Discontinued products are retained in the platform and reason(s) for suspension are provided when available.

Trial Information

Meddevicetracker covers planned, ongoing or completed clinical trials designed to support commercialization. Trial profiles contain detailed trial design information and previous/upcoming milestones. Results data are captured for laboratory and clinical studies. Trial sites and individual investigator details are excluded.

Regulatory and Marketing Information

Meddevicetracker covers regulatory filings, approvals and launches. Voting outcomes from FDA Advisory Committee meetings are captured.

Inclusions:

- PMA / 510(k)
- De Novo and Humanitarian Device Exemption (HDE) approvals
- CE Mark approvals
- Japanese approvals

Exclusions:

- Manufacturing approvals
- Post-marketing requirements

Licensing Information

Meddevicetracker covers licensing and regional distribution agreements in which development and/or commercialization rights are exchanged. Mergers and acquisitions between companies or for a specific product are also covered.

Event and Catalyst Types

Meddevicetracker is built on historical events as well as forward-looking events (or catalysts). Events are categorized by the specific type of information reported in the public domain, such as regulatory, trial data or trial announcements. A complete list of Meddevicetracker [event](#) and [catalysts](#) types along with their definitions is available in the 'Resources' section of the site.