# October 2026 FDA PMA Approvals Report

FDA Premarket Approval decisions and postapproval lifecycle activity | November 2026

## Executive summary

FDA's October 2026 PMA extract contains 221 decisions: three original PMA approvals and 218 supplements or 30-day notices. Of these, 71 decisions are coded APPR and 150 are coded OK30.

The distinction matters: the majority of recorded activity concerns modifications to already-approved devices, not newly approved products.

| October decision metric | Count | Share |
|---|---|---|
| **Total decisions** | 221 | 100% |
| **Original PMA approvals** | 3 | 1.4% |
| **Supplements and notices** | 218 | 98.6% |
| **APPR decision code** | 71 | 32.1% |
| **OK30 decision code** | 150 | 67.9% |

**Scope and counting rule:** Records were selected where DECISIONDATE falls from October 1 through October 31, 2026. Each PMA/supplement record is counted once. This is a decision-month cohort, not a submission cohort, approval rate, or inventory of devices newly marketed in October.

## 1 | Original PMA approvals

| PMA | Applicant | Device | Decision |
|---|---|---|---|
| **P260007** | Edwards Lifesciences, LLC | Autus Size-Adjustable Valve | 10/01/2026 |
| **P250015** | Vivasure Medical , Ltd. | PerQseal® Elite Vascular Closure Device | 10/16/2026 |
| **P260019** | ABBOTT MEDICAL | Amplatzer Paraclose PVL Occluder | 10/27/2026 |

These three original approvals are the clearest candidates for individual device profiles. The extract identifies the applicants, devices, and approval dates; device-specific indications and clinical evidence should be checked against FDA approval orders before describing clinical significance.

## 2 | Regulatory pathways and decision types

| Pathway / submission category | Decisions | Share of all |
|---|---|---|
| **30-Day Notice** | 150 | 67.9% |
| **Real-Time Process** | 22 | 10.0% |
| **Normal 180 Day Track No User** | 19 | 8.6% |

| Pathway / submission category | Decisions | Share of all |
|---|---|---|
| **Fee** | | |
| Normal 180 Day Track | 13 | 5.9% |
| Special (Immediate Track) | 6 | 2.7% |
| 135 Review Track For 30-Day Notice | 5 | 2.3% |
| Panel Track | 3 | 1.4% |
| Original PMA | 3 | 1.4% |

The 150 30-day notice decisions (67.9% of all decisions) are coded OK30. These should not be reported as 150 original PMA approvals. Real-time, 180-day, special, 135-day and panel-track categories describe supplement review pathways, not separate original PMAs.

## 3 | Why manufacturers filed supplements

| Reason recorded in extract | Decisions | Share of 218 |
|---|---|---|
| Process Change - Manufacturer/Sterilizer/Packager/Supplier | 158 | 72.5% |
| Change Design/Components/Specifications/Material | 28 | 12.8% |
| Postapproval Study Protocol | 14 | 6.4% |
| Labeling Change - Indications/instructions/shelf life/tradename | 13 | 6.0% |
| Location Change - Manufacturer/Sterilizer/Packager/Supplier | 4 | 1.8% |
| Labeling Change - PAS | 1 | 0.5% |

Manufacturing, sterilization, packaging and supplier process changes account for 158 of 218 supplement/notice records (72.5%). The leading regulatory intelligence theme is lifecycle change management: process validation, supplier controls, change assessment, and documentation remain significant activities after initial approval.

## 4 | FDA advisory committee distribution

| Review committee | Decisions | Share |
|---|---|---|
| Cardiovascular | 113 | 51.1% |
| Neurology | 30 | 13.6% |
| Ophthalmic | 18 | 8.1% |
| Gastroenterology/Urology | 14 | 6.3% |
| General & Plastic Surgery | 11 | 5.0% |
| All other committee codes | 35 | 15.8% |

Cardiovascular products account for 113 decisions (51.1%), followed by neurology (30) and ophthalmic devices (18). Committee codes are FDA classifications and do not independently establish the therapeutic novelty of each modification.

## 5 | Applicant activity and concentration

| Applicant name as recorded | Decisions |
|---|---|
| Biotronik, Inc. | 21 |
| ABBOTT MEDICAL | 19 |
| Medtronic, Inc. | 18 |
| Edwards Lifesciences, LLC | 14 |
| Medtronic Neuromodulation | 9 |
| Boston Scientific Corp | 6 |
| Medtronic Vascular, Inc. | 6 |
| Berlin Heart, Inc. | 5 |
| Depuy, Inc. | 5 |
| Medtronic Cardiac Rhythm Disease Management | 5 |

Applicant names have not been consolidated across subsidiaries, acquisitions, or spelling variants. Rankings should therefore be interpreted as raw-name frequencies, not definitive parent-company market shares. Multiple notices may relate to a common underlying manufacturing change across device families.

## 6 | Elapsed calendar time

**30-Day Notice:** median 28 calendar days (n=150; range 5–43).

**Real-Time Process:** median 88 calendar days (n=22; range 35–324).

**Normal 180 Day Track No User Fee:** median 89 calendar days (n=19; range 26–280).

**Normal 180 Day Track:** median 217 calendar days (n=13; range 168–484).

**Special (Immediate Track):** median 28 calendar days (n=6; range 15–30).

**135 Review Track For 30-Day Notice:** median 322 calendar days (n=5; range 174–491).

**Panel Track:** median 180 calendar days (n=3; range 178–244).

Elapsed days are calculated as DECISIONDATE minus DATERECEIVED. They are not FDA active-review days, statutory review clocks, or a controlled comparison of pathway performance. Supplement types have different eligibility criteria and operational workflows.

## 7 | Patterns, anomalies and interpretation

**Lifecycle activity dwarfs new approvals.** Only three of 221 decisions are original PMAs; 218 relate to supplements or notices.

**Process changes are the dominant reason.** The 158 manufacturing/process entries represent nearly three-quarters of supplement and notice decisions.

**Cardiovascular concentration is pronounced.** More than half of all October records carry the CV committee code.

**Decision code and pathway must not be conflated.** OK30 denotes a 30-day notice outcome, not approval of a new PMA device.

**Potential clustering merits follow-up.** Multiple records from the same applicant may reflect related changes spanning several approved products; counting records is not the same as counting distinct engineering projects.

**Interpret timing carefully.** Calendar-day intervals can include applicant response time and administrative periods; outliers warrant record-level verification.

**Company normalization is necessary.** The same corporate family may appear under multiple applicant names.

**Clinical significance needs primary documents.** The text extract includes approval statements, but complete indications, labeling and evidence require approval-order and summary review.

## 8 | Implications for regulatory and quality professionals

The October cohort illustrates a practical regulatory reality: FDA market authorization is a milestone, not the end of regulatory responsibility. Maintaining PMA devices involves ongoing evaluation of manufacturing and supplier changes, design modifications, labeling, postapproval commitments, and selection of the correct submission mechanism.

For MDP Regulatory Intelligence, the next analytical step is to profile the three original approvals and examine the largest manufacturer and technology clusters at the individual-record level. Such follow-up can distinguish routine lifecycle maintenance from changes with greater clinical or technological significance.

## Methods, limitations and source

Source: user-provided FDA pipe-delimited PMA extract (pma(1).txt), analyzed November 2026. Selection: DECISIONDATE in October 2026; counts by PMANUMBER and SUPPLEMENTNUMBER. Original approvals are records with no supplement number. Supplement reasons, review categories, applicant names, and decision codes are reproduced from the supplied fields.

Limitations: This extract is a snapshot and may be revised by FDA. It does not provide an appropriate denominator for approval rates, establish review-clock performance, or by itself verify clinical novelty or manufacturing locations. Data-driven observations are descriptive, not causal. Counts may differ from FDA web summaries if those use different extraction dates, filters, or definitions.

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