Full October 2026 PMN Report

November 4, 2026

FDA 510(k) clearances and De Novo grants | Decision dates: October 1–30, 2026

Executive summary

The FDA monthly decision extract contains 295 unique October 2026 decisions: 293 substantial-equivalence (510(k)) clearances and two De Novo classification grants. The 295 figure is a combined decision total, not a count of 510(k) clearances alone. Traditional 510(k)s dominate the PMN subset, and orthopedic, surgical, cardiovascular, and radiology review panels account for the largest volumes.

Measure	October 2026
All listed decisions	295
510(k) clearances (SESE)	293
De Novo grants (DENG)	2
Distinct submission identifiers	295
Applicant country: United States	155 / 295 (52.5%)
Applicant country: China	61 / 295 (20.7%)

Submission pathway breakdown

FDA extract TYPE	Count	Share of 293 510(k)s
Traditional	238	81.2%
Special	50	17.1%
Dual Track	3	1.0%
Abbreviated	2	0.7%
510(k) total	293	100.0%
De Novo / Direct	2	Not a 510(k)
All decisions	295	—

Interpretation: “Dual Track” is preserved as the FDA extract’s TYPE label and is not silently reassigned to Traditional, Special, or Abbreviated. “Direct” identifies the two De Novo entries and is not a 510(k) category.

Review-panel distribution

Review panel (FDA code)	510(k)s	Share
OR	42	14.3%
SU	40	13.7%
CV	34	11.6%
RA	33	11.3%
NE	25	8.5%

Review panel (FDA code)	510(k)s	Share
DE	24	8.2%
HO	19	6.5%
MI	17	5.8%
GU	13	4.4%
PM	11	3.8%
CH	10	3.4%
OB	7	2.4%

The six leading 510(k) panels are Orthopedic (OR), General & Plastic Surgery (SU), Cardiovascular (CV), Radiology (RA), Neurology (NE), and Dental (DE). Review-panel codes describe the FDA review assignment, not necessarily a unique device technology or clinical use.

Applicant geography

Applicant country code	Decisions	Share
US	155	52.5%
CN	61	20.7%
KR	18	6.1%
DE	9	3.1%
GB	7	2.4%
IL	6	2.0%
TW	5	1.7%
FR	5	1.7%
CH	4	1.4%
BE	3	1.0%

Country reflects the applicant address in the extract, not necessarily the country of manufacture, ownership, or device origin. The United States and China together represent 216 of 295 decisions (73.2%).

Timing patterns and limitations

Traditional: 238 decisions; median elapsed calendar time from date received to decision = 140.5 days (range 1–447).

Special: 50 decisions; median elapsed calendar time from date received to decision = 30 days (range 26–238).

Dual Track: 3 decisions; median elapsed calendar time from date received to decision = 180 days (range 118–183).

Abbreviated: 2 decisions; median elapsed calendar time from date received to decision = 204 days (range 145–263).

Direct: 2 decisions; median elapsed calendar time from date received to decision = 267 days (range 140–394).

These are unadjusted elapsed calendar days, not FDA review-clock days or a valid comparison of statutory review performance. They do not exclude holds, additional-information cycles, or applicant response time; the cohorts also differ in complexity and sample size.

Noteworthy patterns and anomalies

1. Two De Novo decisions within a PMN-labeled extract

DEN250054 (Virtuoso Surgical, Inc.; Virtuoso Endoscopy System, October 30) and DEN260027 (Roche Diagnostics; Elecsys HBsAg II quant II RxDx, October 20) carry decision code DENG. Reporting all 295 as 510(k) clearances would overstate that pathway by two.

2. Special 510(k)s show much shorter observed elapsed time

The Special median is 30 days, versus 140.5 days for Traditional. This is descriptive, not evidence of a causal or performance difference; submission eligibility, completeness, and FDA clock exclusions are not captured.

3. Atypical one-day decision intervals

K263680 (One Coat Bond / One Coat Bond SL) and K263860 (Shining3D Clear Aligner System) show a one-day interval between DATERECEIVED and DECISIONDATE. Both are marked third-party reviewed. These entries warrant source-record checks before drawing conclusions about review speed.

4. One Sunday decision date

K253717 (Endovascular Engineering, Inc.; Helo Return) lists October 11, 2026, a Sunday. The record may reflect an administrative posting or data-entry convention; verify against its FDA decision record.

5. Third-party review is uncommon

Only four of 293 510(k) entries have THIRDPARTY = Y (1.4%). The extract does not identify the reviewing organization or provide enough detail to assess the third-party program.

6. Applicant names need normalization

The file lists 268 distinct applicant strings across 295 decisions. Related organizations and spelling/capitalization variations can fragment manufacturer-level totals; unnormalized counts should not be interpreted as corporate market share.

7. Date coverage and data quality

All 295 decision dates fall in October 2026. The EXPEDITEDREVIEW field is blank for every record, so it cannot support a claim that no expedited reviews occurred. Some names and device descriptions show character-encoding artifacts in the source text.

8. Technology signals are illustrative, not an AI census

Entries include Yomi S Robotic System (K261321), Versius Surgical System (K261252), and multiple imaging/software products. A defensible AI/robotics trend count would require reviewing indications and FDA summaries, not keyword matching device names alone.

Selected decisions for follow-up

Submission	Applicant	Device / rationale
DEN250054	Virtuoso Surgical	Virtuoso Endoscopy System - De Novo
DEN260027	Roche Diagnostics	Elecsys HBsAg II quant II RxDx - De Novo
K261321	Neocis	Yomi S Robotic System - robotic dentistry
K261252	CMR Surgical	Versius Surgical System (Versius Plus) - robotics
K263680	See FDA record	One Coat Bond - one-day interval, third party
K263860	See FDA record	Shining3D Clear Aligner System - one-day interval, third party
K253717	Endovascular Engineering	Helo Return - Sunday decision date

Methodology and reporting cautions

Source: user-provided FDA pipe-delimited monthly PMN decision file, pmnlstmn(4).txt, 295 data rows plus header. Each row was counted once by KNUMBER.

The extract was filtered/checked by DECISIONDATE and categorized using the source TYPE, DECISION, REVIEWADVISECOMM, COUNTRY_CODE, and THIRDPARTY fields.

All percentages state their denominator. No independent FDA record-level verification, previous-month comparison, device-risk classification, or manufacturer-parent normalization was performed.