Report to Congress

Premarket Approval of Pediatric Uses of Devices

FY 2024

Submitted Pursuant to
Section 515A of the Federal Food, Drug, and Cosmetic Act



Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress on the premarket approvals for devices labeled[1] for pediatric use, among other requirements. This report also includes information on the premarket approval of devices where there is a pediatric subpopulation[2] that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. This report includes statistical data on these approvals, which were approved by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) during fiscal year (FY) 2024 (i.e., October 1, 2023, through September 30, 2024). This is the thirteenth such report submitted by FDA to Congress.

As noted in this report, during FY 2024, FDA approved 56 premarket device applications. In particular,

- FDA approved 53 original premarket approval (PMA) applications and panel-track supplements for devices and three (3) humanitarian device exemption (HDE) applications for devices, totaling 56 device approvals.

- Of those 56 device approvals, FDA approved 17 PMA applications and two (2) HDE applications (or 19/56, 34 percent) for devices that were indicated for use in a pediatric population or subpopulation.[3,4]

- Of the remaining 37 device approvals, 36 PMA applications and one (1) HDE application were for devices that were indicated for use solely in adults. Of these 37 device approvals, the 36 PMA applications and one (1) HDE application (or 100 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation that also suffers from such a disease or condition.[5]

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[1] See section 201(k) of the FD&C Act for the definition of *label*; see section 201(m) of the FD&C Act for the definition of *labeling*.

[2] Section 520(m)(6)(E)(i) of the FD&C Act (and 21 CFR 814.3(s)) defines *pediatric patients* as patients 21 years of age or younger at the time of their diagnosis or treatment. Section 515A(c) of the FD&C Act defines, by reference to section 520(m)(6)(E)(ii) of the FD&C Act, a *pediatric subpopulation* as one of the following subpopulations: neonates, infants, children, and adolescents.

[3] More information about these FY 2024 pediatric device approvals, including these devices' review times and the pediatric population for which they were indicated at the time of their initial approval, appears in Appendix A of this report.

[4] See section 515A(a)(3)(C) and 515A(a)(3)(D) of the FD&C Act.

[5] See section 515A(a)(3)(A) of the FD&C Act.

- For seven (7) of the above-mentioned 17 PMA applications approved for a device indicated for use in a pediatric population or subpopulation, FDA relied on data from adults to support its determination that the devices were reasonably assured to be safe and effective in pediatric patients.[6]

- For one (1) of the above-mentioned 17 PMA applications approved for a device indicated for use in a pediatric population or subpopulation, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.[7]

- From the 53 PMA application approvals, three (3) PMA applications were for a device that was indicated solely for a pediatric population and therefore exempted from user fees.[8]

- The median time to review the 17 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days[9] and 230 Total Elapsed Days.[10]

- The median time to review the two (2) HDE applications for devices that were indicated for use in a pediatric population or subpopulation was 226 FDA Days[9] and 437 Total Elapsed Days.[10]

- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports[11] received in FY 2024, there were nine (9) additional devices previously approved before FY 2024 and used in pediatric patients but not labeled for such use for which data available indicated that new approved pediatric labeling could confer a benefit to pediatric patients.[12]

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[6] See section 515A(a)(3)(G) of the FD&C Act.

[7] See section 515A(a)(3)(H) of the FD&C Act.

[8] See section 515A(a)(3)(E) of the FD&C Act. Please note that under section 738(a)(2)(B)(i) of the FD&C Act, HDE applications are exempt from user fees.

[9] FDA's Medical Device User Fee Amendments of 2022 (MDUFA V) commitment letter defined *FDA Days* as calendar days when a submission is considered to be under review at the Agency for submissions that have been filed. Tracking of FDA Days begins on the date of the receipt of the submission or the amendment to the submission that enables the submission to be filed. See FDA's final guidance document entitled *FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals* (October 2022), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals.

[10] See section 515A(a)(3)(F) of the FD&C Act.

[11] PMA applications are subject to any periodic postmarket reporting requirements imposed in the PMA approval order (see 21 CFR 814.82(a) and 21 CFR 814.84(b)). Similarly, under 21 CFR 814.126(b), "the holder of an approved HDE" application must submit a periodic report in accordance with the HDE approval order.

[12] Section 515A(a)(3)(B) of the FD&C Act.

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I. Introduction

The Food and Drug Administration Amendments Act of 2007 (FDAAA) amended section 515A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-1).[1] Section 515A(a)(2) of the FD&C Act, as added by FDAAA, requires persons who are submitting a certain device application and seeking approval for that application to include in their application, if readily available, (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.[2] Section 515A(a)(3) of the FD&C Act, as added by FDAAA, requires the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress on the premarket approvals for devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure.[3] On August 18, 2017, section 515A(a)(3) of the FD&C Act was amended by the FDA Reauthorization Act of 2017 (FDARA) to also require, among other things, FDA to provide, in that annual report, additional information related to devices approved with a pediatric indication.[4] Specifically, section 515A(a)(3) of the FD&C Act, as amended, states that,

> *Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—*
>
> *(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;*
>
> *(B) any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for such use for which the Secretary determines that approved pediatric labeling could confer a benefit to pediatric patients;*

[1] Public Law 110-85, 121 Stat. 859.

[2] Section 520(m)(6)(E)(i) of the FD&C Act (and 21 CFR 814.3(s)) defines *pediatric patients* as patients 21 years of age or younger at the time of their diagnosis or treatment. Section 515A(c) of the FD&C Act defines, by reference to section 520(m)(6)(E)(ii) of the FD&C Act, a *pediatric subpopulation* as one of the following subpopulations: neonates, infants, children, and adolescents.

[3] See section 201(k) of the FD&C Act for the definition of *label*; see section 201(m) of the FD&C Act for the definition of *labeling*.

[4] Public Law 115-52, 131 Stat. 1037.

(C) the number of pediatric devices that receive a humanitarian use exemption under section 520(m) [of the FD&C Act];

(D) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

(E) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v) [of the FD&C Act];

(F) the review time for each device described in subparagraphs (A), (C), (D), and (E);

(G) the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and

(H) the number of devices for which the Secretary relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation.

This is the thirteenth report of FDA submitted to Congress pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. This FY 2024 report, consistent with the requirements under section 515A of the FD&C Act, includes information and accounting on FDA's FY 2024 premarket approvals for devices that were, among other requirements, indicated for use in pediatric patients or that are intended to treat, diagnose, or cure diseases from which pediatric patients suffer.[5] This report also includes background information regarding section 515A of the FD&C Act and FDA's implementation of that provision. Information submitted under section 515A(a) of the FD&C Act assisted in the development of this report.

II. Background

Section 515A of the FD&C Act, and other provisions in FDAAA and FDARA, are intended to encourage the development of devices for use in pediatric patients. For

[5] The phrase *indications for use*, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

example, the House Report for FDAAA described the need for the legislation as follows:[6]

> *Pediatric medical devices are used to treat or diagnose diseases and conditions in patients from birth through age 21. Some products are designed specifically for children, while others are borrowed from adult applications or produced for more general use.*
>
> *Children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices that have not been studied for use in children may not accommodate the unique needs of children, such as allowing for expandable growth, and accommodating their active lifestyles and differing metabolism.*

Section 520(m)(6)(E)(i) of the FD&C Act and 21 CFR 814.3(s) define *pediatric patients*, for device approval purposes, as patients who are 21 years of age or younger (i.e., from birth through the day prior to their 22nd birthday) at the time of diagnosis or treatment. Additionally, a *pediatric subpopulation* is defined by section 520(m)(6)(E)(ii) of the FD&C Act (and adopted by reference in section 515A(c) of the FD&C Act) as one of the following subpopulations: neonates, infants, children, and adolescents. Generally, FDA views the approximate age ranges for these pediatric subpopulations as follows:[7]

- Neonates (birth until 1 month of age);
- Infants (greater than 1 month of age until 2 years of age);
- Children (greater than 2 years of age until 12 years of age); and
- Adolescents (greater than 12 years of age through 21 years of age (i.e., up to but not including the 22nd birthday)).

On January 10, 2014, FDA issued a final rule in the *Federal Register*[8] that amended 21 CFR part 814's regulations on the premarket approval of devices to require persons who are submitting a certain device application and seeking approval for that application to include in their application, if readily available, (1) a description of any pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients. These regulations reflect requirements under section 515A of the FD&C Act, as amended by FDAAA and FDARA.

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[6] House Committee on Energy and Commerce, "Food and Drug Administration Amendments Act of 2007," H.Rept.100-225, 110th Congress, 1st Session, on page 8.

[7] See FDA's final guidance document entitled *Premarket Assessment of Pediatric Medical Devices*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices.

[8] *Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer from a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure* (79 FR 1735 at 1735-1741) (January 10, 2014).

On March 24, 2014, FDA issued a final guidance document entitled *Premarket Assessment of Pediatric Medical Devices*.[9] On May 1, 2014, FDA issued a final guidance document entitled *Providing Information about Pediatric Uses of Medical Devices,* which provides information for applicants regarding the pediatric information requirement mandated under section 515A of the FD&C Act and its implementing regulations.[10]

Lastly, on June 21, 2016, FDA issued a final guidance document entitled *Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices*.[11] This guidance document seeks to provide clarity and predictability for device sponsors and to ensure consistency within FDA regarding the specific criteria that should be considered when deciding whether leveraging existing clinical data to support pediatric device indications in premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, and De Novo requests is appropriate and, if so, to what extent.

III. Summary of the Information Required by Section 515A(a)(3) of the FD&C Act

Consistent with section 515A of the FD&C Act, this report provides data on premarket device approvals that were approved by FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) during FY 2024. In particular, in FY 2024:

- FDA approved 53 original premarket approval (PMA) applications and panel-track supplements for devices and three (3) humanitarian device exemption (HDE) applications for devices, totaling 56 device approvals.

- Of those 56 device approvals, FDA approved 17 PMA applications and two (2) HDE applications (or 19/56, 34 percent) for devices that were indicated for use in a pediatric population or subpopulation.[12,13]

[9] This final guidance document, published in March 2014, is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices.

[10] This final guidance document, published in May 2014, is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-information-about-pediatric-uses-medical-devices.

[11] This final guidance document, published in June 2016, is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/leveraging-existing-clinical-data-extrapolation-pediatric-uses-medical-devices.

[12] More information about these FY 2024 pediatric device approvals, including these devices' review times and the pediatric population for which they were indicated at the time of their initial approval, appears in Appendix A of this report.

[13] See section 515A(a)(3)(C) and 515A(a)(3)(D) of the FD&C Act.

- Of the remaining 37 device approvals, 36 PMA applications and one (1) HDE application were for devices that were indicated for use solely in adults. Of these 37 device approvals, the 36 PMA applications and one (1) HDE application (or 100 percent) were for devices that were determined to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation that also suffers from such a disease or condition.[14]

- For seven (7) of the above-mentioned 17 PMA applications approved for a device indicated for use in a pediatric population or subpopulation, FDA relied on data from adults to support its determination that the devices were reasonably assured to be safe and effective in pediatric patients.[15]

- For one (1) of the above-mentioned 17 PMA applications approved for a device indicated for use in a pediatric population or subpopulation, FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.[16]

- From the 53 PMA application approvals, three (3) PMA applications were for a device that was indicated solely for a pediatric population and therefore exempted from user fees.[17]

- The median time to review the 17 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days[18] and 230 Total Elapsed Days.[19]

- The median time to review the two (2) HDE applications for devices that were indicated for use in a pediatric population or subpopulation was 226 FDA Days[18] and 437 Total Elapsed Days.[19]

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[14] See section 515A(a)(3)(A) of the FD&C Act.

[15] See section 515A(a)(3)(G) of the FD&C Act.

[16] See section 515A(a)(3)(H) of the FD&C Act.

[17] See section 515A(a)(3)(E) of the FD&C Act. Please note that under section 738(a)(2)(B)(i) of the FD&C Act, HDE applications are exempt from user fees.

[18] FDA's Medical Device User Fee Amendments of 2022 (MDUFA V) commitment letter defined *FDA Days* as calendar days when a submission is considered to be under review at the Agency for submissions that have been filed. Tracking of FDA Days begins on the date of the receipt of the submission or the amendment to the submission that enables the submission to be filed. See FDA's final guidance document entitled *FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals* (October 2022), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals.

[19] See section 515A(a)(3)(F) of the FD&C Act.

- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports[20] received in FY 2024, there were 9 additional devices previously approved before FY 2024 and used in pediatric patients but not labeled for such use for which data available indicated that new approved pediatric labeling could confer a benefit to pediatric patients.[21]

From FY 2008 to FY 2024, 869 PMA and HDE applications have been approved by CDRH and CBER combined, with an average of 51.12 device approvals per year.[22] Of these device approvals, 255[23] were approved with an indication for use in a pediatric population or subpopulation at the initial time of the marketing authorization.

Since FY 2008, as shown in Figure 1A, there has generally been an increase in PMA and HDE application approvals for devices with non-pediatric indications reviewed by CDRH and CBER.[24] From FY 2008 to FY 2024, the greatest number (i.e., 73) of PMA or HDE application approvals was in FY 2016, and the lowest number of PMA or HDE application approvals (i.e., 21) was in FY 2010.[25]

[20] PMA applications are subject to any periodic postmarket reporting requirements imposed in the PMA approval order (see 21 CFR 814.82(a) and 21 CFR 814.84(b)). Similarly, under 21 CFR 814.126(b), "the holder of an approved HDE" application must submit a periodic report in accordance with the HDE approval order.

[21] Section 515A(a)(3)(B) of the FD&C Act.

[22] See Table 1 in Appendix B.

[23] This number was obtained by totaling the PMA and HDE application approvals for devices indicated for pediatric patients from FY 2008 to FY 2024; see Table 1 in Appendix B.

[24] See also Table 1 in Appendix B.

[25] These numbers represent the combined PMA or HDE application approvals by CDRH and CBER in FY 2016 and in FY 2010.

Figure 1A demonstrates the PMA and HDE application approvals, from FY 2008 to FY 2024, with pediatric indications (blue) and non-pediatric (red) indications of devices reviewed by CDRH and CBER.

Figure 1A. PMA and HDE Application Approvals from FY 2008 to FY 2024 for Devices with Pediatric Indications and Non-Pediatric Indications.

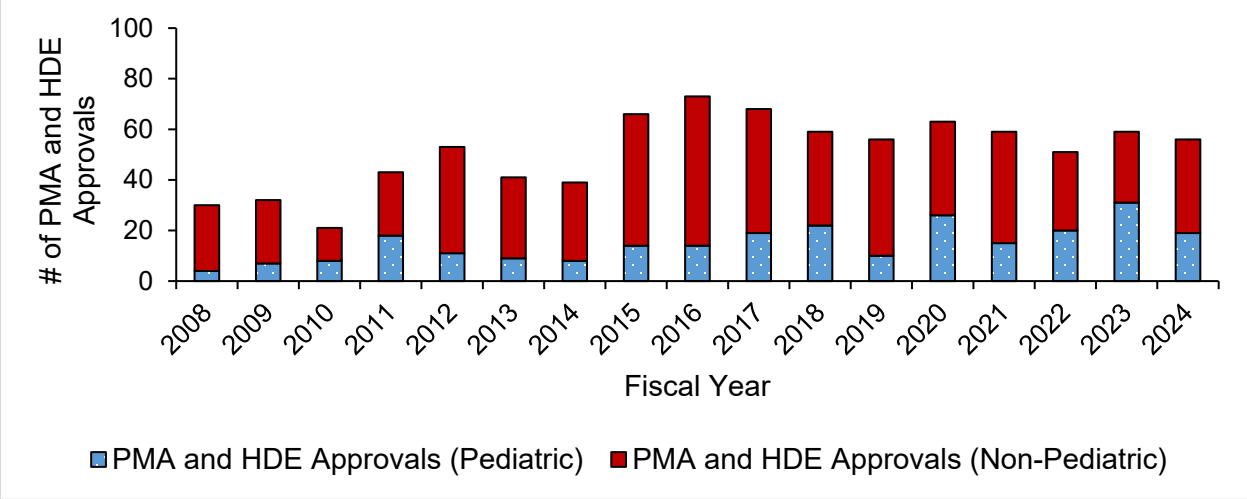
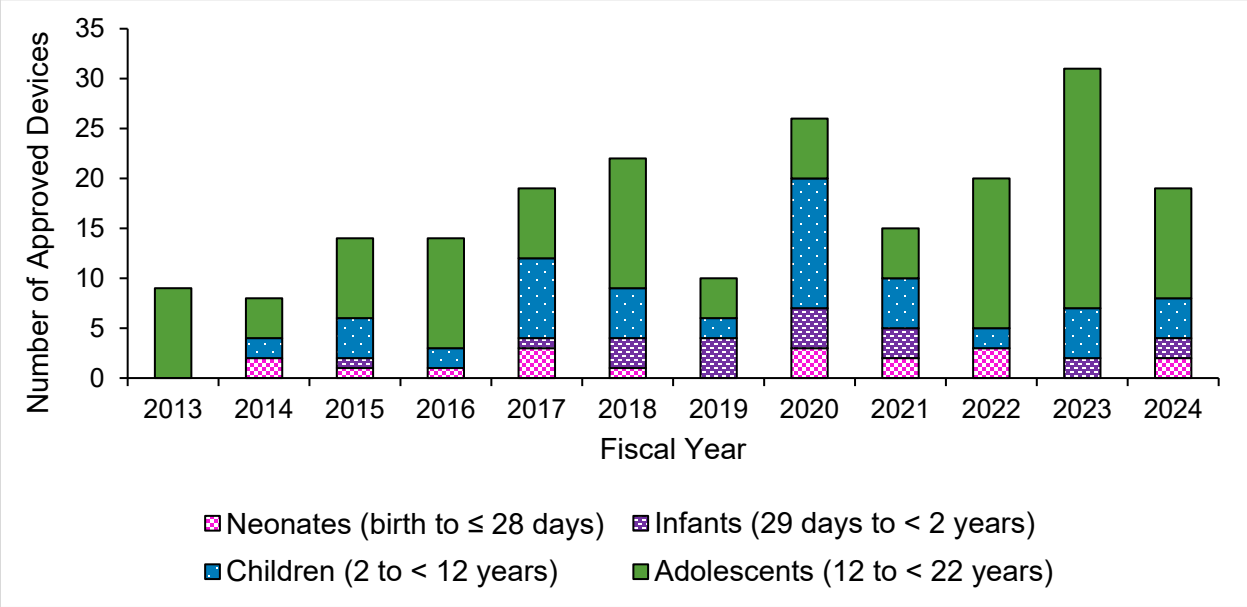


Figure 1B shows, by the age of each pediatric subpopulation, the PMA and HDE application approvals for devices indicated for these subpopulations; these devices were reviewed by CDRH and CBER from FY 2013 to FY 2024. The PMA and HDE application approvals are categorized by the youngest age for which there was an indication for use. In rare cases, a device may have only been used in a specific subpopulation.[26]

[26] See also Table 2 of Appendix B for a more detailed breakdown, by the age of each pediatric subpopulation, of PMA and HDE application approvals for devices indicated for these subpopulations; these devices were reviewed by CDRH and CBER from FY 2013 to FY 2024.

Figure 1B. PMA and HDE Application Approvals by the Youngest Suggested Pediatric Subpopulation from FY 2013 to FY 2024.



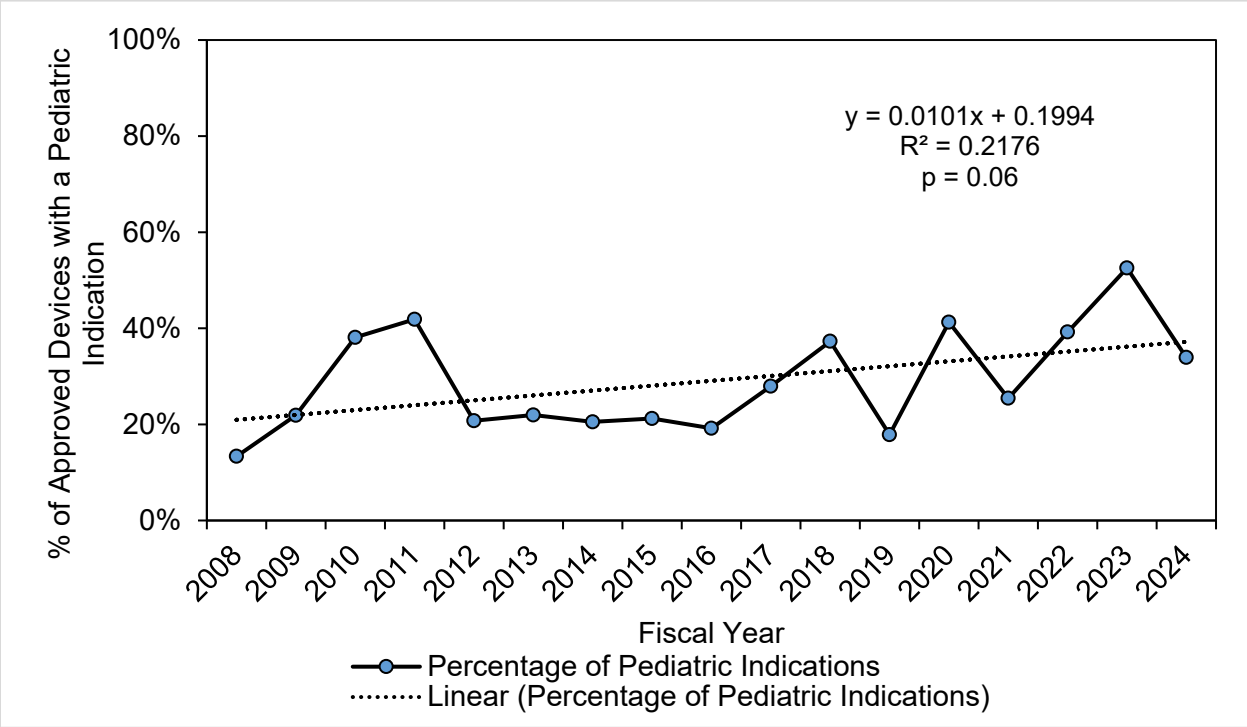
Appendix A includes a detailed summary of each of the FY 2024 PMA and HDE application approvals for devices that were indicated for use in a pediatric population or pediatric subpopulation.

Since FY 2008, the largest number (i.e., 31) of PMA and HDE application approvals by CDRH and CBER for devices with an indication that included a pediatric population or subpopulation was in FY 2023.[27] As shown in Figure 2 (below), the largest percentage of PMA and HDE application approvals (i.e., 53%) for devices with an indication that included a pediatric population or subpopulation was in FY 2023.[28]

[27] See Table 1 in Appendix B.

[28] See also Table 1 in Appendix B.

Figure 2. Percentage of PMA and HDE Applications Indicated for Use Within the Pediatric Population (Mean = 29% (255/869)).



On average for the last 17 fiscal years, only 29 percent of the total PMA and HDE application approvals in each fiscal year have been for a device with an indication that includes a pediatric population or subpopulation. After increasing during FYs 2008–2011, pediatric approvals declined to 21 percent in FY 2012. Since then, the percentage has fluctuated, ranging from 18 percent (FY 2019) to 53 percent (FY 2023), with the most recent data showing 34 percent in FY 2024.

IV. Conclusion

Since FY 2008, FDA has submitted reports to Congress providing information concerning FDA's annual premarket approvals of devices that were indicated for pediatric use. This thirteenth such report, submitted under section 515A(a)(3) of the FD&C Act, includes data on the devices approved by CDRH and CBER, in FY 2024, that had an indication for use in the pediatric population or its subpopulations. Based on the information summarized in this report, there have been limited changes since FY 2008 in FDA's PMA or HDE application approvals for devices indicated for use in a pediatric population or subpopulation. Since the passage of FDAAA, the number of devices approved for the pediatric population has generally increased; however, the trend has remained relatively constant due to the variability in the percentage of devices

indicated for use in the pediatric population, out of the total number of devices approved each fiscal year.[29]

FDA is committed to continue working with the pediatrics community to support the advancement, development, and availability of devices for use in the pediatric population. FDA takes seriously its responsibility to ensure that the devices on the market, including those for the pediatric population, demonstrate a reasonable assurance of safety and effectiveness. For the latest information on FDA's efforts related to pediatric devices, refer to FDA's Pediatric Medical Devices web page.[30]

[29] See Table 1 in Appendix B.

[30] https://www.fda.gov/medical-devices/products-and-medical-procedures/pediatric-medical-devices.

Appendix A: Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations in FY 2024

All devices included in this appendix are approved and labeled for use in a pediatric population.[31] Below, CDRH and CBER include information on the youngest suggested pediatric subpopulations for the listed devices, as designated under section 515A(c) of the FD&C Act, based on these Centers' analyses of publicly available information, such as the device's Summary of Safety and Effectiveness Data, Summary of Safety and Probable Benefit, and labeling, as well as additional factors, including but not limited to average pediatric anthropometric measurements and device dimensions. Generally, FDA views the approximate age ranges for these pediatric subpopulations as follows:[32]

- Neonates (birth until 1 month of age);
- Infants (greater than 1 month of age until 2 years of age);
- Children (greater than 2 years of age until 12 years of age); and
- Adolescents (greater than 12 years of age through 21 years of age (i.e., up to but not including the 22nd birthday)).

CDRH Device Information

FoundationOne®CDx (F1CDx)

FoundationOne®CDx (F1CDx) is a qualitative next-generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens when using the DNAx extraction method. The test is intended for detection of substitutions and indels in 324 genes, CNAs in 15 genes and select gene rearrangements, as well as genomic signatures including MSI and TMB using DNA isolated from FFPE tumor tissue specimens when using the CoExtraction method for DNA isolation. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 [below] in

[31] Additional information pertaining to these devices can be found in the Summary of Safety and Effectiveness Data or the Summary of Safety and Probable Benefit by searching the PMA or HDE number, respectively. The PMA and HDE application approvals are listed in chronological order from the earliest approval date. In addition, please consult FDA's Medical Device Databases web (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases) for more information.

[32] See FDA's final guidance document entitled *Premarket Assessment of Pediatric Medical Devices*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices.

accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Table 1. Companion diagnostic indications

Tumor Type	Biomarker(s) Detected	Therapy
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	EGFR Tyrosine Kinase Inhibitors (TKI) approved by FDA*
	EGFR exon 20 T790M alterations	Tagrisso® (osimertinib)
	ALK rearrangements	Alecensa® (alectinib), Alunbrig® (brigatinib), Xalkori® (crizotinib), or Zykadia® (ceritinib)
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)
	MET single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping	Tabrecta® (capmatinib)
	ROS1 fusions	Rozlytrek® (entrectinib)
Melanoma	*BRAF* V600E	BRAF Inhibitors approved by FDA*
	BRAF V600E and V600K	Mekinist® (trametinib) or BRAF/MEK Inhibitor Combinations approved by FDA*
	BRAF V600 mutation-positive	Tecentriq® (atezolizumab) in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)
Breast cancer	*ERBB2* (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)
	PIK3CA C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y Alterations	Piqray® (alpelisib)

Colorectal cancer	*KRAS* wild-type (absence of mutations in codons 12 and 13)	Erbitux® (cetuximab)
	KRAS wild-type (absence of mutations in exons 2, 3, and 4) and NRAS wild type (absence of mutations in exons 2, 3, and 4)	Vectibix® (panitumumab)
Ovarian Cancer	*BRCA1/2* alterations	Lynparza® (olaparib)
Cholangiocarcinoma	*FGFR2* fusions and select rearrangements	Pemazyre® (pemigatinib) or Truseltiq™ (infigratinib)
Prostate cancer	Homologous Recombination Repair (HRR) gene (*BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D* and *RAD54L*) Alterations	Lynparza® (olaparib)
	BRCA1, BRCA2 alterations	Akeega® (niraparib + abiraterone acetate)
Solid Tumors	MSI-High	Keytruda® (pembrolizumab)
	TMB 2' 10 mutations per megabase	Keytruda® (pembrolizumab)
	NTRK1/2/3 fusions	Rozlytrek® (entrectinib) Vitrakvi® (larotrectinib)
	RET fusions	Retevmo® (selpercatinib)

*For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion- diagnostic-devices-in-vitro-and-imaging-tools

The test is also used for detection of genomic loss of heterozygosity (LOH) from formalin-fixed, paraffin-embedded (FFPE) ovarian tumor tissue. Positive homologous recombination deficiency (HRD) status (F1CDx HRD defined as tBRCA-positive and/or LOH high) in ovarian cancer patients is associated with improved progression-free survival (PFS) from Rubraca (rucaparib) maintenance therapy in accordance with the Rubraca product label.

The F1CDx assay is performed at Foundation Medicine, Inc. sites located in Cambridge, MA and Morrisville, NC.

Manufacturer	Foundation Medicine, Inc.
Number	P170019/S043
Filing Date	03/02/2023
Approval Date	10/06/2023

Youngest Suggested Pediatric Subpopulation	Adolescents[33]
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	177
Total Elapsed Days	218

FoundationOne® Liquid CDx

FoundationOne Liquid CDx is a qualitative next generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report genomic alterations in 311 genes. These include substitutions, insertions and deletions (indels) in 311 genes, rearrangements in 8 genes, and copy number alterations in 3 genes. FoundationOne Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne Liquid CDx cfDNA blood collection tubes included in the FoundationOne Liquid CDx Blood Sample Collection Kit. The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 [below] in accordance with the approved therapeutic product labeling.

Table 1: Companion diagnostic indications

Tumor Type	Biomarker(s) Detected	Therapy
Non-small cell lung cancer (NSCLC)	*ALK* Rearrangements	ALECENSA® (alectinib)
	BRAF V600E	BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib)
	EGFR Exon 19 deletions and *EGFR* Exon 21 L858R substitution	*EGFR* tyrosine kinase inhibitors approved by FDA*
	EGFR Exon 20 insertions	EXKIVITY® (mobocertinib)
	MET single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping	TABRECTA® (capmatinib)
	ROS1 fusions**	ROZLYTREK® (entrectinib)
Prostate cancer	*BRCA1*, *BRCA2*, and *ATM* alterations	LYNPARZA® (olaparib)
	BRCA1, *BRCA2* alterations	RUBRACA® (rucaparib)

[33] This panel-track supplement was submitted to expand the indication for F1CDx to include a companion diagnostic (CDx) indication for the detection of RET fusions in patients with solid tumors who may benefit from treatment with RETEVMO® (selpercatinib).

Breast Cancer	*PIK3CA* mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y	PIQRAY® (alpelisib)
Solid Tumors	*NTRK1/2/3* fusions**	ROZLYTREK® (entrectinib)
Colorectal cancer (CRC)	*BRAF* V600E	BRAFTOVI ® (encorafenib) in combination with cetuximab

*For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion- diagnostic-devices-in-vitro-and-imaging-tools#Group_Labeling

Additionally, FoundationOne Liquid CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms.

A negative result from a plasma specimen does not mean that the patient's tumor is negative for genomic findings. Patients who are negative for the mutations listed in Table 1 (see **Note for *NTRK1/2/3* and *ROS1* fusions) should be reflexed to routine biopsy and their tumor mutation status confirmed using an FDA-approved tumor tissue test, if feasible.

**Note: when considering eligibility for ROZLYTREK® based on the detection of *NTRK1/2/3* and *ROS1* fusions, testing using plasma specimens is only appropriate for patients for whom tumor tissue is not available for testing.

Genomic findings other than those listed in Table 1 of the intended use statement are not prescriptive or conclusive for labeled use of any specific therapeutic product.

FoundationOne Liquid CDx is a single-site assay performed at Foundation Medicine, Inc. in Cambridge, MA.

Manufacturer	Foundation Medicine, Inc.
Number	P190032/S011
Filing Date	02/23/2023
Approval Date	10/11/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)[34]
Exempt from User Fees Because Intended Solely for Pediatric Use?	No

[34] This panel-track supplement was submitted to expand the indication for the F1LCDx test as a companion diagnostic for the detection of BRAF V600E in patients with non-small cell lung cancer (NSCLC) who may benefit from treatment with BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib).

FDA Days	208
Total Elapsed Days	230

FoundationOne®CDx (F1CDx)

FoundationOne®CDx (F1CDx) is a qualitative next-generation sequencing based *in vitro* diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens when using the DNAx extraction method. The test is intended for detection of substitutions and indels in 324 genes, CNAs in 16 genes and select gene rearrangements, as well as genomic signatures including MSI and TMB using DNA isolated from FFPE tumor tissue specimens when using the CoExtraction method for DNA isolation. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 [below] in accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Table 1. Companion diagnostic indications

Tumor Type	Biomarker(s) Detected	Therapy
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	EGFR Tyrosine Kinase Inhibitors (TKI) approved by FDA*
	EGFR exon 20 T790M alterations	TAGRISSO® (osimertinib)
	ALK rearrangements	ALECENSA® (alectinib), ALUNBRIG® (brigatinib) XALKORI® (crizotinib), or ZYKADIA® (ceritinib)
	BRAF V600E	BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib)
		TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	MET single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping	TABRECTA™ (capmatinib)

	ROS1 Fusions	ROZLYTREK® (entrectinib)
Melanoma	*BRAF* V600E	BRAF Inhibitors approved by FDA*
	BRAF V600E and V600K	MEKINIST® (trametinib) or BRAF/MEK Inhibitor Combinations approved by FDA*
	BRAF V600 mutation-positive	TECENTRIQ® (atezolizumab) in combination with COTELLIC®
		(cobimetinib) and ZELBORAF® (vemurafenib)
Breast cancer	*ERBB2* (HER2) amplification	HERCEPTIN® (trastuzumab), KADCYLA® (ado-trastuzumabemtansine), or PERJETA® (pertuzumab)
	PIK3CA C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y alterations	PIQRAY® (alpelisib)
	AKT1 E17K, *PIK3CA* R88Q, N345K, C420R, E542K, E545A, E545D, E545Q, E545K, E545G, Q546E, Q546K, Q546R, Q546P, M1043V, M1043I, H1047Y, H1047R, H1047L, and G1049R; and *PTEN* alterations	TRUQAP™ (capivasertib) in combination with FASLODEX® (fulvestrant)
Colorectal cancer	*KRAS* wild-type (absence of mutations in codons 12 and 13)	ERBITUX® (cetuximab)
	KRAS wild-type (absence of mutations in exons 2, 3, and 4) and *NRAS* wild type (absence of mutations in exons 2, 3, and 4)	VECTIBIX® (panitumumab)

Ovarian cancer	*BRCA1/2* alterations	LYNPARZA® (olaparib)
Cholangiocarcinoma	*FGFR2* fusions and select rearrangements	PEMAZYRE® (pemigatinib) or TRUSELTIQ™ (infigratinib)
Prostate cancer	Homologous Recombination Repair (HRR) gene (*BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D* and *RAD54L*) Alterations	LYNPARZA® (olaparib)
	BRCA1, BRCA2 alterations	AKEEGA® (niraparib + abiraterone acetate)
Solid tumors	MSI-High	KEYTRUDA® (pembrolizumab)
	TMB 2' 10 mutations per megabase	KEYTRUDA® (pembrolizumab)
	NTRK1/2/3 fusions	ROZLYTREK® (entrectinib) or VITRAKVI® (larotrectinib)
	RET fusions	RETEVMO® (selpercatinib)

*For the most current information about the therapeutic products in this group, go to: https://www.fda.gov/medicaldevices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

The F1CDx assay is performed at Foundation Medicine, Inc. sites located in Cambridge, MA and Morrisville, NC.

Manufacturer	Foundation Medicine, Inc.
Number	P170019/S048
Filing Date	07/03/2023
Approval Date	11/16/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)[35]
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	136
Total Elapsed Days	136

[35] This panel-track supplement was submitted to expand the indication for F1CDx to include a companion diagnostic (CDx) claim for the detection of PIK3CA/AKT1/PTEN-alterations in patients with breast cancer who may benefit from treatment with TRUQAP™ (capivasertib) in combination with FASLODEX® (fulvestrant).

CALCIVIS Imaging System

The CALCIVIS Imaging System is intended to be used by dental healthcare professionals on patients (6 years and older) with, or at risk of developing, demineralization associated with caries lesions, on accessible coronal tooth surfaces.

The CALCIVIS Imaging System is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis, monitoring and treatment planning of demineralization associated with caries lesions.

Manufacturer	CALCIVIS Limited
Number	P170029/S003
Filing Date	09/12/2023
Approval Date	10/13/2023
Youngest Suggested Pediatric Subpopulation	Children (6 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	31
Total Elapsed Days	31

Aurora EV-ICD™ System

The Aurora EV-ICD™ System is comprised of the following:

- Aurora EV-ICD™ MRI SureScan™ DVEA3E4 Extravascular Implantable Cardioverter Defibrillator (EV-ICD)
- Aurora EV-ICD Application Software SW041 v8.4
- Epsila EV™ MRI SureScan™ EV2401 Extravascular lead
- Epsila EV™ EAZ101 Sternal Tunneling Tool
- Epsila EV™ EAZ201 Transverse Tunneling Tool Shield™

The Aurora EV-ICD™ MRI SureScan™ DVEA3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include:

- Previous ventricular tachyarrhythmias
- Coronary disease with left ventricular dysfunction
- Cardiomyopathy
- Inherited primary arrhythmia syndromes
- Congenital heart disease

Note: For patient-specific recommendations regarding indications for primary and secondary prevention of sudden cardiac death, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS).

The Epsila EV™ MRI SureScan™ Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias.

The Epsila EV EAZ101 Sternal Tunneling Tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

The Epsila EV EAZ201 Transverse Tunneling Tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

Manufacturer	Medtronic, Inc.
Number	P220012
Filing Date	08/12/2022
Approval Date	10/20/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	178
Total Elapsed Days	434

AvertD™ and AvertD™ Buccal Sample Collection Kit

AvertD™ is a prescription, qualitative genotyping test used to detect and identify 15 genetic polymorphisms in genomic DNA isolated from buccal samples collected from individuals 18 years of age and older. The test may be used as part of a clinical evaluation and risk assessment to identify patients who may be at elevated risk for developing opioid use disorder (OUD). The test is indicated for use only in patients prior to receiving a first prescription of oral opioids for 4-30 days for acute pain, such as in patients scheduled to undergo a planned surgical procedure and who consent to having the test performed.

The AvertD™ Buccal Sample Collection Kit is intended for use in the non-invasive collection, transport and storage of buccal specimens. DNA from the buccal sample will be suitable for use in AvertD. Buccal samples are collected by a qualified healthcare professional. For use only in individuals 18 years or older.

Manufacturer	AutoGenomics, Inc.
Number	P230032
Filing Date	09/25/2023
Approval Date	12/19/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	85

Total Elapsed Days	85

Occlutech® ASD Occluder and Occlutech® Pistol Pusher

The Occlutech® ASD Occluder is a medical device intended for transcatheter closure of ostium secundum-type atrial septal defects (ASD). Patients indicated for ASD closure have:

- echocardiographic evidence of ostium secundum-type ASD,
- clinical evidence of right ventricular (RV) volume overload (hemodynamically significant left-to-right shunt with Qp / Qs ≥ 1.5 or RV enlargement).

The Occlutech® Pistol Pusher is a percutaneous, transcatheter pusher system designed for the delivery of the Occlutech® ASD Occluder to the implantation area. It is used via a minimally invasive catheter delivery system technique.

Manufacturer	Occlutech Holding AG
Number	P200032
Filing Date	07/07/2020
Approval Date	12/29/2023
Youngest Suggested Pediatric Subpopulation	Children
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	188
Total Elapsed Days	1270

TZ Medical Adult Multi-Function Defibrillation Electrodes and Adaptors and TZ Medical Pediatric Multi-Function Defibrillation Electrodes and Adaptors

TZ Medical disposable electrodes are intended for use by trained professionals in hospitals, doctor's offices and Emergency Medical Services for low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.

TZ Medical Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control LIFEPAK (LP) defibrillators are compatible with Physio-Control / Stryker LP 15, LP 20, LP 20E, LP 1000, LP CR Plus, and LP Express defibrillators.

TZ Medical Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control / Stryker defibrillators are compatible with Physio-Control LP 15, LP 20, and LP 20e defibrillators.

TZ Medical Adult Multi-Function Defibrillation Electrodes with connectors intended for use with ZOLL defibrillators are compatible with ZOLL R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators.

TZ Medical Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with ZOLL defibrillators are compatible with ZOLL R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators.

TZ Medical Multi-Function Defibrillation Electrodes are designed for single use with multiple defibrillators for biphasic defibrillation, pacing, monitoring, or cardioversion either directly or through adaptors.

Manufacturer	TZ Medical, Inc.
Number	P200005
Filing Date	02/04/2021
Approval Date	01/09/2024
Youngest Suggested Pediatric Subpopulation	Infants
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	185
Total Elapsed Days	1069

PyloPlus® UBT System

The PyloPlus® UBT system is intended for use in the qualitative detection of urease associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis and post treatment monitoring of H. pylori infection in adults and pediatric patients ages 3-17 years old. The PyloPlus® UBT system consists of the PyloPlus® UBT Kit and the PyloPlus® UBT analyzer. The analyzer is an infrared Spectrometer used for the measurement of the ratio of 13CO2 to 12CO2 in breath samples. The PyloPlus® UBT system is for use by trained health care professionals as prescribed by a physician.

Manufacturer	ARJ Medical, Inc.
Number	P170022/S003
Filing Date	07/17/2023
Approval Date	01/11/2024
Youngest Suggested Pediatric Subpopulation	Children (3 years and older)[36]
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	178
Total Elapsed Days	178

[36] This panel-track supplement was submitted to expand the indication to pediatrics ages 3-17 years old.

INTELLANAV STABLEPOINT™ Ablation Catheter & Force Sensing System on the RHYTHMIA HDX™ Mapping System

The INTELLANAV STABLEPOINT Catheter, when used with a compatible Radiofrequency Controller and Irrigation Pump, is indicated for:

- Cardiac electrophysiological mapping
- Delivering pacing stimuli
- RF ablation of sustained or recurrent typical atrial flutter in patients age 18 or older
- Treatment of drug refractory, recurrent, symptomatic, Paroxysmal Atrial Fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.

Manufacturer	Boston Scientific Corporation
Number	P150005/S074
Filing Date	02/09/2023
Approval Date	02/26/2024
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	382

Saluda Medical Evoke® SCS System

The Saluda Medical Evoke SCS System is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following:

- Failed back surgery syndrome
- Intractable low back and leg pain
- Diabetic peripheral neuropathy of the lower extremities

Manufacturer	Saluda Medical Pty Ltd.
Number	P190002/S019
Filing Date	09/22/2023
Approval Date	03/20/2024
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	180

LIAISON Biotrin Parvovirus B19 IgG Plus
LIAISON Biotrin Control Parvovirus B19 IgG Plus

LIAISON Biotrin Parvovirus B19 IgG Plus

The LIAISON Biotrin Parvovirus B19 IgG Plus, a chemiluminescent immunoassay (CLIA), is intended for the qualitative detection of IgG antibodies to B19 virus (B19V, previously known as human parvovirus B19) in human serum, lithium heparin, dipotassium EDTA (K2-EDTA), and sodium citrated plasma. The test may be used for testing women of childbearing age where there is a suspicion of exposure to human B19V. The test may also be used for all patients as an aid in the diagnosis of fifth disease (erythema infectiosum). The test must be performed on the LIAISON XL Analyzer.

LIAISON Biotrin Control Parvovirus B19 IgG Plus

The LIAISON Biotrin Control Parvovirus B19 IgG Plus (negative and positive) is intended for use as assayed quality control samples to monitor the performance and reliability of LIAISON Biotrin Parvovirus B19 IgG Plus assay. The performance characteristics of LIAISON Biotrin Control Parvovirus B19 IgG Plus have not been established for any other assays or instrument platforms different from the automated LIAISON XL Analyzer.

Manufacturer	DiaSorin, Inc.
Number	P220034
Filing Date	12/27/2022
Approval Date	03/29/2024
Youngest Suggested Pediatric Subpopulation	Children
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	179
Total Elapsed Days	458

nAbCyte Anti-AAVRh74var HB-FE Assay

The nAbCyte Anti-AAVRh74var HB-FE Assay for BEQVEZ™ (fidanacogene elaparvovec) Eligibility in moderate to severe Hemophilia B, or nAbCyte AntiAAVRh74var HB-FE Assay, is a cell-based qualitative in vitro companion diagnostic device intended for the detection of neutralizing antibodies to the AAVRh74var capsid in serum specimens from adult patients previously diagnosed with moderate to severe hemophilia B to determine eligibility for treatment with the hemophilia B gene therapy, BEQVEZ (fidanacogene elaparvovec). Patients who test positive for neutralizing antibodies to the AAVRh74var capsid are not eligible for treatment with BEQVEZ (fidanacogene elaparvovec). Patients who test negative for neutralizing antibodies to the AAVRh74var capsid are eligible for treatment with BEQVEZ (fidanacogene elaparvovec).

This diagnostic device is a single-site assay for professional use only and is to be performed only at Labcorp-Monogram Biosciences by trained and qualified laboratory

personnel.

Manufacturer	Labcorp Drug Development
Number	H230005
Filing Date	07/26/2023
Approval Date	04/25/2024
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	171
Total Elapsed Days	274

Simplera system

The Simplera system is a real-time continuous glucose monitoring (CGM) system indicated for the management of diabetes in persons ages 18 years and older.

The Simplera system does not require calibration and is designed to replace fingerstick blood glucose (BG) testing for diabetes treatment decisions, unless otherwise indicated.

Interpretation of the Simplera system results should be based on the glucose trends and several sequential sensor readings over time.

Manufacturer	Medtronic MiniMed, Inc.
Number	P160007/S047
Filing Date	03/14/2023
Approval Date	07/24/2024
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	498

MAGE-A4 IHC 1F9 pharmDx

For in vitro diagnostic use.

MAGE-A4 IHC IF9 pharmDx is a qualitative immunohistochemical (IHC) assay using monoclonal mouse anti-MAGE-A4, Clone OTI1F9, intended for use in the detection of MAGE-A4 protein in formalin-fixed, paraffin-embedded (FFPE) synovial sarcoma tissue using the EnVision FLEX visualization system on Autostainer Link 48. MAGE-A4 protein expression in synovial sarcoma is determined by using the MAGE-A4 Tumor Intensity Proportion Score (TIPS), which is the overall percentage of viable tumor cells showing MAGE-A4 nuclear and/or cytoplasmic staining at staining intensity ≥ 2+. The specimen should be considered positive if MAGE-A4 TIPS (≥ 2+) is ≥ 75%.

MAGE-A4 IHC 1F9 pharmDx is indicated as an aid in identifying patients with synovial sarcoma for whom TECELRA® (afamitresgene autoleucel), a MAGE-A4-directed genetically modified autologous T-cell immunotherapy, is being considered.

See the TECELRA® product label for specific clinical circumstances guiding MAGE-A4testing.

Manufacturer	Agilent Technologies, Inc.
Number	P230016
Filing Date	05/01/2023
Approval Date	08/01/2024
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	458

TruSight™ Oncology Comprehensive

TruSight Oncology Comprehensive is a qualitative in vitro diagnostic test that uses targeted next-generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumor tissue samples from cancer patients with solid malignant neoplasms using the Illumina® NextSeq™ 550Dx instrument. The test can be used to detect single nucleotide variants, multi- nucleotide variants, insertions, and deletions from DNA, and fusions in 24 genes and splice variants in one gene from RNA. The test also reports a Tumor Mutational Burden (TMB) score.

The test is intended to be used as a companion diagnostic to identify cancer patients who may benefit from treatment with the targeted therapies listed in Table 1, in accordance with the approved therapeutic product labeling.

In addition, the test is intended to provide tumor profiling information for use by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 [below] of the intended use statement are not conclusive or prescriptive for labeled use of any specific therapeutic product.

Table 1. Companion Diagnostic Indications

Tumor Type	Biomarker(s) Detected	Therapy
Solid Tumors	*NTRK1/2/3 fusions*	VITRAKVI® (larotrectinib)
Non-Small Cell Lung Cancer (NSCLC)	*RET fusions*	RETEVMO® (selpercatinib)

Manufacturer	Illumina Inc.
Number	P230011
Filing Date	03/20/2023
Approval Date	08/21/2024
Youngest Suggested Pediatric Subpopulation	Neonates • VITRAKVI Adolescents (18 years and older) • RETEVMO
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	520

Renata Minima Stent System

The Minima Stent System is indicated for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight.

Manufacturer	Renata Medical, Inc.
Number	P240003
Filing Date	03/01/2024
Approval Date	08/28/2024
Youngest Suggested Pediatric Subpopulation	Neonates (1.5 kg and above)
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	180
Total Elapsed Days	180

CBER Device Information

QUELIMMUNE

The SCD-PED is intended to treat pediatric patients (weight ≥ 10 kg and age ≤ 22 years) with acute kidney injury (AKI) due to sepsis or a septic condition on antibiotic therapy and requiring renal replacement therapy (RRT).

Manufacturer	SeaStar Medical, Inc
Number	BH220740/0
Filing Date	07/01/2022
Approval Date	02/21/2024
Youngest Suggested Pediatric Subpopulation	Infants (10 kg and above)
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes

FDA Days	281
Total Elapsed Days	600

RECELL® Autologous Cell Harvesting Device

The RECELL Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL Device is used by an appropriately licensed and trained healthcare professional at the patient's point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older, or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing tissue infection) or resection (e.g., skin cancer) in patients 15 years of age and older.

Manufacturer	AVITA Medical Americas, LLC.
Number	BP170122/575
Filing Date	07/03/2023
Approval Date	12/22/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (15 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	172
Total Elapsed Days	172

Appendix B: PMA and HDE Application Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2024 by CDRH and CBER

Table 1. Total PMA and HDE Application Approvals and PMA and HDE Application Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2024 (per Center).

Fiscal Year	Approved PMA and HDE Devices by Center		Total Approved PMA and HDE Devices	Approved Pediatric PMA and HDE Devices by Center		Total Approved Pediatric PMA and HDE Devices
	CDRH	CBER		CDRH	CBER	
2008	29	1	30	4	0	4 (13%)
2009	31	1	32	7	0	7 (22%)
2010	20	1	21	7	1	8 (38%)
2011	41	2	43	17	1	18 (42%)
2012	52	1	53	11	0	11 (21%)
2013	39	2	41	8	1	9 (22%)
2014	37	2	39	8	0	8 (21%)
2015	61	5	66	11	3	14 (21%)
2016	71	2	73	13	1	14 (19%)
2017	66	2	68	18	1	19 (28%)
2018	57	2	59	20	2	22 (37%)
2019	55	1	56	10	0	10 (18%)
2020	60	3	63	24	2	26 (41%)
2021	53	6	59	11	4	15 (25%)
2022	50	1	51	19	1	20 (39%)

2023	57	2	59	29	2	31 (53%)
2024	54	2	56	17	2	19 (34%)

In Table 2, the devices were categorized by the youngest age for which there was an indication for use.[37]

Table 2. PMA and HDE Application Approvals Indicated for Pediatric Subpopulations by Age from FY 2013 to FY 2024.

Pediatric Subpopulation	PMA	HDE	Total
FY 2013			
Neonates (birth to ≤ 28 days)	**0**	**0**	**0**
Infants (29 days to < 2 years)	**0**	**0**	**0**
Children (2 to < 12 years)	**0**	**0**	**0**
Adolescents (12 to < 22 years)	**9**	**0**	**9**
FY 2014			
Neonates (birth to ≤ 28 days)	**1**	**1**	**2**
Infants (29 days to < 2 years)	**0**	**0**	**0**
Children (2 to < 12 years)	**1**	**1**	**2**
Adolescents (12 to < 22 years)	**4**	**0**	**4**
FY 2015			
Neonates (birth to ≤ 28 days)	**1**	**0**	**1**
Infants (29 days to < 2 years)	**1**	**0**	**1**
Children (2 to < 12 years)	**4**	**0**	**4**
Adolescents (12 to < 22 years)	**7**	**1**	**8**
FY 2016			
Neonates (birth to ≤ 28 days)	**0**	**1**	**1**
Infants (29 days to < 2 years)	**0**	**0**	**0**
Children (2 to < 12 years)	**2**	**0**	**2**
Adolescents (12 to < 22 years)	**11**	**0**	**11**
FY 2017			
Neonates (birth to ≤ 28 days)	**2**	**1**	**3**
Infants (29 days to < 2 years)	**1**	**0**	**1**
Children (2 to < 12 years)	**8**	**0**	**8**
Adolescents (12 to < 22 years)	**6**	**1**	**7**
FY 2018			
Neonates (birth to ≤ 28 days)	**1**	**0**	**1**
Infants (29 days to < 2 years)	**3**	**0**	**3**

[37] The youngest age for which the devices were approved occurred within the age range for each pediatric subpopulation, not necessarily the minimum age.

Children (2 to < 12 years)	**4**	**1**	**5**
Adolescents (12 to < 22 years)	**13**	**0**	**13**
FY 2019			
Neonates (birth to ≤ 28 days)	**0**	**0**	**0**
Infants (29 days to < 2 years)	**4**	**0**	**4**
Children (2 to < 12 years)	**1**	**1**	**2**
Adolescents (12 to < 22 years)	**3**	**1**	**4**
FY 2020			
Neonates (birth to ≤ 28 days)	**3**	**0**	**3**
Infants (29 days to < 2 years)	**4**	**0**	**4**
Children (2 to < 12 years)	**13**	**0**	**13**
Adolescents (12 to < 22 years)	**6**	**0**	**6**
FY 2021			
Neonates (birth to ≤ 28 days)	**2**	**0**	**2**
Infants (29 days to < 2 years)	**2**	**1**	**3**
Children (2 to < 12 years)	**5**	**0**	**5**
Adolescents (12 to < 22 years)	**5**	**0**	**5**
FY 2022			
Neonates (birth to ≤ 28 days)	**2**	**1**	**3**
Infants (29 days to < 2 years)	**0**	**0**	**0**
Children (2 to < 12 years)	**2**	**0**	**2**
Adolescents (12 to < 22 years)	**15**	**0**	**15**
FY 2023			
Neonates (birth to ≤ 28 days)	**0**	**0**	**0**
Infants (29 days to < 2 years)	**2**	**0**	**2**
Children (2 to < 12 years)	**4**	**1**	**5**
Adolescents (12 to < 22 years)	**24**	**0**	**24**
FY 2024			
Neonates (birth to ≤ 28 days)	**2**	**0**	**2**
Infants (29 days to < 2 years)	**1**	**1**	**2**
Children (2 to < 12 years)	**4**	**0**	**4**
Adolescents (12 to < 22 years)	**10**	**1**	**11**

This report was prepared by FDA's Center for Devices and Radiological Health, in coordination with FDA's Center for Biologics Evaluation and Research. For more information, please contact:

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