Report to Congress

Premarket Approval of Pediatric Uses of Devices

FY 2022 – FY 2023

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) 2022 (i.e., October 1, 2021, through September 30, 2022) and FY 2023 (October 1, 2022, through September 30, 2023). This is the twelfth such report submitted by FDA to Congress.

As noted in this report, during FY 2022 and FY 2023, FDA granted 110 premarket device approvals. In particular, in FY 2022,

- FDA approved 50 original premarket approval (PMA) applications and panel-track supplements for devices and one humanitarian device exemption (HDE) application for devices, totalling 51 device approvals.

- Of those 51 device approvals, FDA approved 20 PMA applications and no HDE applications (or 20/51, 39 percent) for devices that were indicated for use in a pediatric population or subpopulation.[3,4]

- Of the remaining 31 device approvals, 30 PMA applications and one HDE application were for devices that were indicated for use in adults. Of these 31 device approvals, the 30 PMA applications and one 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 21 CFR 1.3 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 2021 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 11 of the above-mentioned 20 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 of the above-mentioned 20 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 50 PMA application approvals, one PMA application for a device that was indicated solely for a pediatric population was exempted from user fees.[8]

- The median time to review the 20 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 179 FDA Days[9] and 266 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 2022, there were 16 additional devices previously approved 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]

In FY 2023,

- FDA approved 57 original PMA applications and panel-track supplements for devices and two HDE applications for devices, totalling 59 device approvals.

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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 2017 (MDUFA IV) 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 2017), 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.

- Of those 59 device approvals, FDA approved 30 PMA applications and one HDE application (or 31/59, 53 percent) for devices that were indicated for use in a pediatric population or subpopulation.

- Of the remaining 28 device approvals, 27 PMA applications and one HDE application were for devices that were indicated for use in adults. Of these 28 device approvals, the 27 PMA applications and one 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.

- For 15 of the above-mentioned 30 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 device was reasonably assured to be safe and effective in pediatric patients.

- For none of the above-mentioned 30 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 its determination that the device was reasonably assured to be safe and effective in another pediatric subpopulation.

- From the 57 PMA application approvals, four PMA applications for devices that were indicated solely for a pediatric population were exempted from user fees.

- The median time to review the 30 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days and 292 Total Elapsed Days.

- The median time to review the one HDE application for a device that was indicated for use in a pediatric population or subpopulation was 289 FDA Days and 641 Total Elapsed Days.

- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports received in FY 2023, there were 14 additional devices previously approved 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.

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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 now also require, among other things, FDA to provide, in that annual report, information related to the number of 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 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 21 CFR 1.3 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 twelfth report of FDA submitted to Congress pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. This combined fiscal year (FY) 2022 and FY 2023 report, consistent with the requirements under section 515A of the FD&C Act, includes information and accounting on FDA's FY 2022 and FY 2023 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.

[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.

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 example, the Congressional 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 years. 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 now 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

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[6] House Committee on Energy and Commerce, "Food and Drug Administration Amendments Act of 2007," H.R.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).

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.

On March 24, 2014, FDA issued a final guidance document entitled *Premarket Assessment of Pediatric 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.[9] On May 1, 2014, FDA issued a final guidance document entitled *Providing Information about Pediatric Uses of Medical Devices*.[10]

Later, 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 2022 and FY 2023:

A. FY 2022

- FDA approved 50 original premarket approval (PMA) applications and panel-track supplements for devices and one humanitarian device exemption (HDE) application for devices, totalling 51 device approvals.

[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.

- Of those 51 device approvals, FDA approved 20 PMA applications and no HDE applications (or 20/51, 39 percent) for devices that were indicated for use in a pediatric population or subpopulation.[12,13]

- Of the remaining 31 device approvals, 30 PMA applications and one HDE application were for devices that were indicated for use in adults. Of these 31 device approvals, the 30 PMA applications and one 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 11 of the above-mentioned 20 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 of the above-mentioned 20 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 50 PMA application approvals, one PMA application for a device that was indicated solely for a pediatric population was exempted from user fees.[17]

- The median time to review the 20 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 179 FDA Days[18] and 266 Total Elapsed Days. [19]

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[12] More information about these FY 2021 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.

[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 2017 (MDUFA IV) 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 2017), 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 2022, there were 16 additional devices previously approved 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]

B. FY 2023

- FDA approved 57 original PMA applications and panel-track supplements for devices and two HDE applications, totalling 59 device approvals.

- Of those 59 device approvals, FDA approved 30 PMA applications and one HDE application (or 31/59, 53 percent) for devices that were indicated for use in a pediatric population or subpopulation.

- Of the remaining 28 device approvals, 27 PMA applications and one HDE application were for devices that were indicated for use in adults. Of these 28 device approvals, the 27 PMA applications and one 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.

- For 15 of the above-mentioned 30 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 device was reasonably assured to be safe and effective in pediatric patients.

- For none of the above-mentioned 30 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 its determination that the device was reasonably assured to be safe and effective in another pediatric subpopulation.

- From the 57 PMA application approvals, four PMA applications for devices that were indicated solely for a pediatric population were exempted from user fees.

- The median time to review the 30 PMA applications for devices that were indicated for use in a pediatric population or subpopulation was 180 FDA Days and 292 Total Elapsed Days.

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[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.

- The median time to review the one HDE for a device that was indicated for use in a pediatric population or subpopulation was 289 FDA Days and 641 Total Elapsed Days.[22]

- Based on a review of the data available to FDA, such as the PMA and HDE periodic reports received in FY 2023, there were 14 additional devices previously approved 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.

From FY 2008 to FY 2023, 813 PMA and HDE applications have been approved by CDRH and CBER combined, with an average of 50.81 device approvals per year.[23] Of these device approvals, 236[24] 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.[25] From FY 2008 to FY 2023, 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.[26]

Figure 1A demonstrates the PMA and HDE application approvals, from FY 2008 to FY 2023, with pediatric indications (blue) and non-pediatric (red) indications of devices reviewed by CDRH and CBER.

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

[23] See Table 1 in Appendix B.

[24] This number was obtained by totaling the PMA and HDE application approvals for devices indicated for pediatric patients from FY 2008 to FY 2021; see Table 1 in Appendix B.

[25] See also Table 1 in Appendix B.

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

Figure 1A. PMA and HDE Application Approvals from FY 2008 to FY 2023 for Devices with Pediatric Indications and Non-Pediatric Indications.

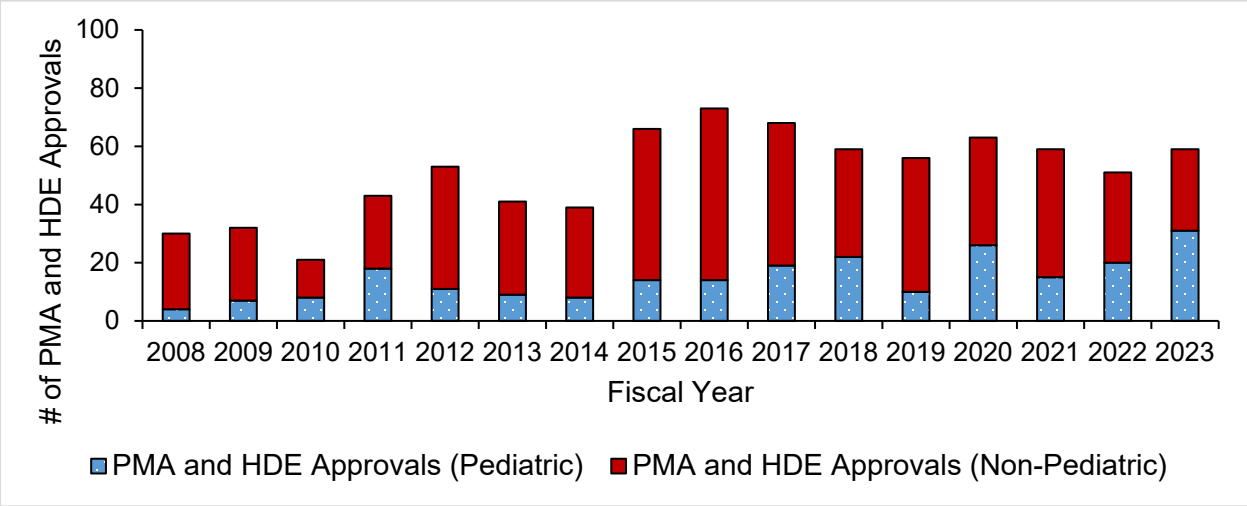
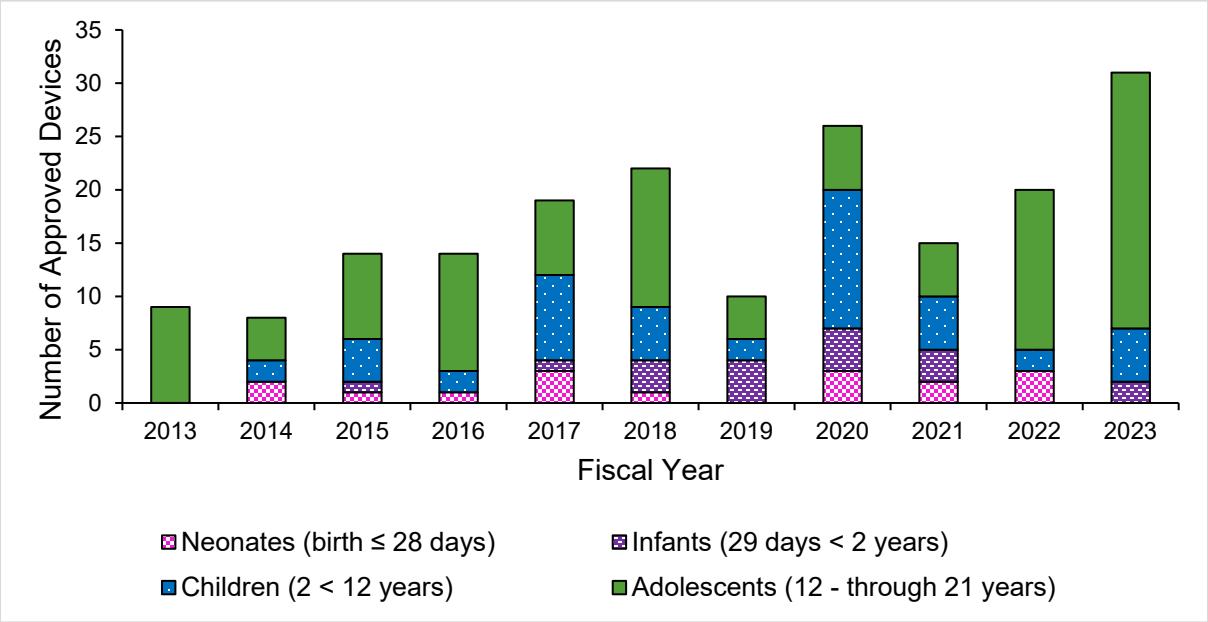


Figure 1B shows, by the age of each pediatric subpopulation, the PMA and HDE application approvals for devices indicated for these subpopulations; these devices were reviewed by CDRH and CBER from FY 2008 to FY 2023. The PMA and HDE application approvals are categorized by the youngest age for which there was an indication for use. In rare cases, a device may have only been used in a specific subpopulation.[27]

[27] 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 2023.

Figure 1B. PMA and HDE Application Approvals by the Youngest Suggested Pediatric Subpopulation from FY 2013 to FY 2023.



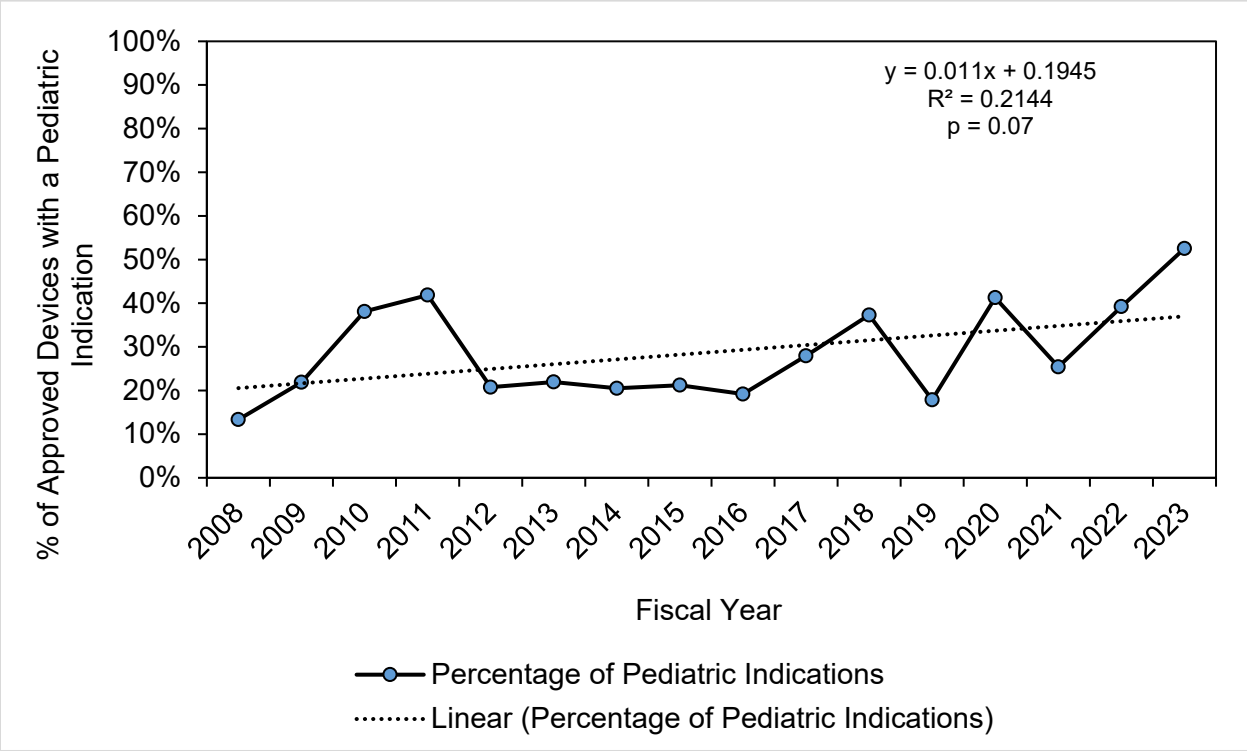
Appendix A includes a detailed summary of each of the FY 2022 and FY 2023 PMA and HDE application approvals for devices that were indicated for use in a pediatric population or pediatric subpopulation.

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.[28] As shown in Figure 2, 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.[29]

[28] See Table 1 in Appendix B.

[29] See also Table 1 in Appendix B.

Figure 2. Percentage of PMA and HDE Applications Indicated for Use Within the Pediatric Population (Mean = 29% (236/813)).



On average for the last 16 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. The percentage of pediatric indications increased between FY 2008 and FY 2011, but starting in FY 2012, the percentage of PMA and HDE application approvals for devices with pediatric indications declined to 21 percent, only rising again to 28 percent in FY 2017 and 37 percent in FY 2018. The percentage of pediatric indications decreased to 18 percent in FY 2019, increased to 41 percent in FY 2020, decreased to 25 percent in FY 2021, and started rising again to 39 percent in FY 2022 and 53 percent in FY 2023.

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 twelfth 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 2022 and FY 2023, 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 percentage of devices indicated for use in the pediatric population, out of the total number of devices approved each fiscal year, has remained relatively constant.[30]

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.[31]

[30] See Table 1 in Appendix B.

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

Appendix A: The Devices Indicated for Use in Pediatric Populations Approved from FY 2022 to FY 2023

A. FY 2022 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations

All devices included in this appendix are approved and labeled for use in a pediatric population.[32] 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.

FY 2022

CDRH Device Information

Ki-67 IHC MIB-1 pharmDx (Dako Omnis)

For In Vitro Diagnostic Use.

Ki-67 IHC MIB-1 pharmDx (Dako Omnis) is a qualitative immunohistochemical (IHC) assay using monoclonal mouse anti-Ki-67, Clone MIB-1, intended for use in the detection of Ki-67 protein in formalin-fixed, paraffin-embedded (FFPE) breast carcinoma tissue using the EnVision FLEX visualization system on Dako Omnis.

Ki-67 protein expression in breast carcinoma is determined by using the Ki-67 pharmDx Score, which is the overall percentage of viable tumor cells in the invasive cancer component showing Ki-67 nuclear staining. The specimen should be considered to have Ki67 expression if Ki-67 pharmDx Score is ≥ 20%.

Ki-67 IHC MIB-1 pharmDx (Dako Omnis) is indicated as an aid in identifying patients with early breast cancer at high risk of disease recurrence for whom adjuvant treatment with Verzenio® (abemaciclib) in combination with endocrine therapy is being considered.

[32]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.

Manufacturer	Agilent Technologies, Inc.
Number	P210026
Filing Date	06/30/2021
Approval Date	10/12/2021
Youngest Suggested Pediatric Subpopulation	Adolescents (17 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	104
Total Elapsed Days	104

VENTANA PD-L1 (SP263) Assay

VENTANA PD-L1 (SP263) Assay is a qualitative immunohistochemistry assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the programmed death ligand-1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue specimens by light microscopy. The VENTANA PD-L1 (SP263) Assay is used with the OptiView DAB IHC Detection Kit for staining on the BenchMark ULTRA instrument.

PD-L1 protein expression in NSCLC is determined by the percentage of tumor cells (% TC) with any membrane staining above background.

VENTANA PD-L1 (SP263) assay is indicated as an aid in identifying patients eligible for treatment with the therapy listed in Table 1 for the indication and PD-L1 status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA PD-L1 (SP263) Assay Companion Diagnostic Indication

Indication for Use	PD-L1 Cut-off	Therapy
NSCLC	≥ 1% TC	TECENTRIQ (atezolizumab)

Results of the VENTANA PD-L1 (SP263) Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for in vitro diagnostic (IVD) use.

Manufacturer	Ventana Medical Systems, Inc.
Number	P160046/S010
Filing Date	06/14/2021
Approval Date	10/15/2021
Youngest Suggested Pediatric Subpopulation	Adolescents (17 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	123
Total Elapsed Days	123

OrganOx metra® System

The OrganOx metra® is a transportable device intended to be used to sustain donor livers destined for transplantation in a functioning state for a total preservation time of up to 12 hours.

The OrganOx metra® device is suitable for liver grafts from donors after brain death (DBD), or liver grafts from donors after circulatory death (DCD) ≤40 years old, with ≤20 mins of functional warm ischemic time (time from donor systolic blood pressure <50 mmHg), and macrosteatosis ≤15%, in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.

Manufacturer	OrganOx Limited
Number	P200035
Filing Date	07/17/2020
Approval Date	12/09/2021
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	510

Edwards SAPIEN 3 Transcatheter Heart Valve System with Edwards Commander Delivery System

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

Manufacturer	Edwards Lifesciences, LLC
Number	P200015/S011
Filing Date	06/21/2021
Approval Date	12/16/2021
Youngest Suggested Pediatric Subpopulation	Adolescents (17 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	178
Total Elapsed Days	178

Nucleus 24 Cochlear Implant System

The Cochlear Nucleus 24 Cochlear Implant System is indicated for individuals with unilateral hearing loss who meet the following criteria:

- Individuals 5 years or older who have one ear with a severe to profound sensorineural hearing loss and obtain limited benefit from an appropriately fitted unilateral hearing device and one ear with normal or near normal hearing.
    - In the ear to be implanted, a severe to profound sensorineural hearing loss defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz of > 80 dB HL.
    - In the contralateral ear, normal or near normal hearing is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz ≤ 30 Db HL.
- Limited benefit from an appropriately fit unilateral hearing device is defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant (CNC) word test. For individuals between 5 years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
- It is recommended that prior to cochlear implantation, individuals with SSD have at least two (2) weeks to one (1) month experience wearing appropriately fit Contralateral Routing of Signal (CROS) hearing aid or another suitable hearing device (i.e., traditional hearing aid).

Manufacturer	Cochlear Americas
Number	P970051/S205
Filing Date	05/28/2021
Approval Date	01/10/2022
Youngest Suggested Pediatric Subpopulation	Children (5 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	227

Prometra Programmable Infusion Pump System

The Prometra® Programmable Infusion Pump System is indicated for intrathecal infusion of drug therapy, including: Infumorph® (preservative free morphine sulfate sterile solution), preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP), and baclofen (baclofen injection, intrathecal, 500-2000 mcg/mL). For Infumorph, the pump system is indicated for use in patient populations of 22 years and older (adults). For baclofen and 0.9% saline solution, the pump system is indicated for use in patient populations of 12 years and older (adolescents and adults).

The approved drug labeling governs the indications, contraindications, warnings and precautions related to the use of the drug.

Manufacturer	Algorithm Sciences, Inc.
Number	P080012/S068
Filing Date	11/16/2020
Approval Date	01/12/2022
Youngest Suggested Pediatric Subpopulation	Adolescents
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	180
Total Elapsed Days	422

ITREL(R) Totally Implantable Spinal Cord Stimulation System

This device is indicated for spinal cord stimulation (SCS) systems 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 conditions:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia
- Diabetic peripheral neuropathy of the lower extremities

Manufacturer	Medtronic Neuromodulation
Number	P840001/S469
Filing Date	08/10/2021
Approval Date	01/21/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	164
Total Elapsed Days	164

Eversense E3 Continuous Glucose Monitoring System

The Eversense® E3 CGM System is intended for continually measuring glucose levels in adults (18 years and older) with diabetes for up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The system is intended for single patient use.

Manufacturer	Senseonics, Incorporated
Number	P160048/S016
Filing Date	10/08/2020
Approval Date	02/10/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	490
Total Elapsed Days	490

FoundationOne CDx

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. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 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	Gilotrif® (afatinib), Iressa® (gefitinib), Tagrisso® (osimertinib), or Tarceva® (erlotinib)
	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)
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) or Rubraca® (rucaparib)
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)
Solid tumors	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)
	NTRK1/2/3 fusions	Vitrakvi® (larotrectinib)
	MSI-High	Keytruda® (pembrolizumab)

*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-companiondiagnostic-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 will be performed at Foundation Medicine, Inc. sites located in Cambridge, MA and Morrisville, NC.

Manufacturer	Foundation Medicine, Inc.
Number	P170019/S029
Filing Date	04/19/2021
Approval Date	02/18/2022
Youngest Suggested Pediatric Subpopulation	Neonates
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	178
Total Elapsed Days	305

Et Control

The optional Et Control feature is designed to interface with the Aisys CS2 Anesthesia System to support clinicians in maintaining the targeted end tidal oxygen and end tidal anesthetic agent concentrations that the clinician sets during an anesthetic procedure,

by making multiple, limited adjustments to the fresh gas composition and total flow. The Et Control feature is indicated for patients, 18 years of age and older.

Manufacturer	Datex-Ohmeda, Inc.
Number	P210018
Filing Date	05/03/2021
Approval Date	03/17/2022
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	318

Organ Care System (OCS) Heart System

The TransMedics Organ Care System (OCS) Heart is indicated for the preservation of donation-after-brain-death (DBD) hearts initially deemed unsuitable for procurement and transplantation at initial evaluation due to limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time). The OCS Heart System is also indicated for the ex vivo reanimation, functional monitoring, and beating-heart preservation of donation-after-circulatory-death (DCD) hearts.

Manufacturer	TransMedics, Inc.
Number	P180051/S001
Filing Date	11/08/2021
Approval Date	04/27/2022
Youngest Suggested Pediatric Subpopulation	Adolescents
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	170
Total Elapsed Days	170

FoundationOne CDx

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. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 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

Indication	**Biomarker**	**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* wildtype (absence of mutations in exons 2, 3, and 4)	VECTIBIX® (panitumumab)
Ovarian cancer	*BRCA1/2* alterations	LYNPARZA® (olaparib) or RUBRACA® (rucaparib)
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)
Solid tumors	TMB > 10 mutations per megabase	KEYTRUDA® (pembrolizumab)
	NTRK1/2/3 fusions	ROZLYTREK® (entrectinib) or VITRAKVI® (larotrectinib)
	MSI-High	KEYTRUDA® (pembrolizumab)

*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-companiondiagnostic-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 will be performed at Foundation Medicine, Inc. sites located in Cambridge, MA and Morrisville, NC.

Manufacturer	Foundation Medicine, Inc.
Number	P170019/S014
Filing Date	12/16/2019
Approval Date	06/07/2022
Youngest Suggested Pediatric Subpopulation	Adolescents
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	762
Total Elapsed Days	904

LungFit PH

The LungFit® PH is intended to deliver nitric oxide, a vasodilator, generated by the device into the inspiratory limb of the patient breathing circuit of a ventilator in a way that provides a constant concentration of nitric oxide, as set by the user, to the patient throughout the inspired breath.

The LungFit® PH provides continuous integrated monitoring of inspired O2, NO2 and NO, and a comprehensive alarm system.

The LungFit® PH includes an integrated backup NO delivery system that is a completely independent backup NO generating system; it has its own NO generator and gas flow delivery system. The backup flow is delivered at 1 L/min at 220ppm NO to either a ventilator circuit or to a bagging system, depending upon the user selected setting.

The NO generated by the LungFit® PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

Manufacturer	Beyond Air, Inc.
Number	P200044
Filing Date	11/17/2020
Approval Date	06/28/2022
Youngest Suggested Pediatric Subpopulation	Neonates
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	201
Total Elapsed Days	588

ARCHITECT HBsAg NEXT Qualitative Reagent Kit, ARCHITECT HBsAg NEXT Confirmatory Reagent Kit, ARCHITECT HBsAg NEXT Qualitative Calibrators, ARCHITECT HBsAg NEXT Qualitative Controls, ARCHITECT HBsAg NEXT Confirmatory Manual Diluent

ARCHITECT HBsAg NEXT Qualitative Reagent Kit

The HBsAg Next Qualitative assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 years to 21 years of age) serum, serum separator tube, and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator, sodium heparin) on the ARCHITECT i System.

The assay may also be used to screen for hepatitis B virus (HBV) infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HBV (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection.

WARNING: Not approved for use in screening blood, plasma, tissue donors, or cadaveric specimens.

ARCHITECT HBsAg NEXT Confirmatory Reagent Kit

The HBsAg Next Confirmatory assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 years to 21 years of age) serum, serum separator, and plasma (dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator, sodium heparin) by means of specific antibody neutralization on the ARCHITECT i System.

Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with the hepatitis B virus (HBV) (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. It is intended to be used for the confirmation of samples found to be repeatedly reactive by HBsAg Next Qualitative.

It is intended to be used for the confirmation of samples found to be repeatedly reactive by HBsAg Next Qualitative.

WARNING: Not approved for use in screening blood, plasma, tissue donors, or cadaveric specimens. The effectiveness of the ARCHITECT HBsAg Next Confirmatory assay for use in screening blood, plasma, or tissue donors has not been established.

ARCHITECT HBsAg NEXT Qualitative Calibrators

The HBsAg Next Qualitative Calibrators are for the calibration of the ARCHITECT i System when used for qualitative determination and confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma.

ARCHITECT HBsAg NEXT Qualitative Controls

The HBsAg Next Qualitative Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the qualitative detection and for the confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma.

ARCHITECT HBsAg NEXT Confirmatory Manual Diluent

The HBsAg Next Confirmatory Manual Diluent is used for manually diluting specimens for testing on the ARCHITECT i System.

Manufacturer	Abbott Laboratories
Number	P210003
Filing Date	02/08/2021
Approval Date	08/10/2022
Youngest Suggested Pediatric Subpopulation	Children
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	214
Total Elapsed Days	548

Oncomine™ Dx Target Test

The Oncomine™ Dx Target Test is a qualitative in vitro diagnostic test that uses targeted high throughput, parallel-sequencing technology to detect single nucleotide variants (SNVs), insertions, and deletions in 23 genes from DNA and fusions in ROS1 and in RET from RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor samples from patients with non-small cell lung cancer (NSCLC), and IDH1 SNVs from FFPE tumor tissue samples from patients with cholangiocarcinoma (CC), using the Ion PGM™ Dx System.

The test is indicated as a companion diagnostic to aid in selecting NSCLC and CC patients for treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. List of Variants for Therapeutic Use

Tissue Type	Gene	Variant	Targeted Therapy
NSCLC	*BRAF*	*BRAF* V600E mutation	TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	EGFR	*EGFR* L858R mutation, *EGFR exon* 19 deletions	IRESSA® (gefitinib)

NSCLC	*EGFR*	*EGFR* exon 20 insertions	EXKIVITY™ (mobocertinib)
			RYBREVANT™ (amivantamab-vmjw)
	ERBB2/HER2	*ERBB2/HER2* activating mutations (SNVs and exon 20 insertions)	ENHERTU® (famtrastuzumab deruxtecannxki)
	RET	*RET* fusions	GAVRETO™ (pralsetinib)
	ROS1	*ROS1* fusions	XALKORI® (crizotinib)
CC	*IDH1*	*IDH1 R132C, IDH1 R132G, IDH1 R132H IDH1 R132L*, and *IDH1 R132S* mutations	TIBSOVO® (ivosidenib)

Safe and effective use has not been established for selecting therapies using this device for the variants other than those in Table 1.

Results other than those listed in Table 1 are indicated for use only in patients who have already been considered for all appropriate therapies (including those listed in Table 1).

Analytical performance using NSCLC specimens has been established for the variants listed in Table 2.

Table 2. List of Variants with Established Analytical Performance Only

Gene	Variant Type	Amino Acid Change	Nucleotide Change
KRAS	COSM512	p.Gly12Phe	c.34_35delGGinsTT
KRAS	COSM516	p.Gly12Cys	c.34G>T
MET	COSM707	p.Thr1010Ile	c.3029C>T
PIK3CA	COSM754	p.Asn345Lys	c.1035T>A

The test is not indicated to be used for standalone diagnostic purposes, screening, monitoring, risk assessment, or prognosis.

Manufacturer	Life Technologies Corporation
Number	P160045/S035
Filing Date	03/08/2022
Approval Date	08/11/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	108
Total Elapsed Days	156

Guardant360 CDx

Guardant360® CDx is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360® CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. Companion Diagnostic Indications

Indication	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions, L858R, and T790M*	TAGRISSO® (osimertinib)
	EGFR exon 20 insertions R	RYBREVANTTM (amivantamab-vmjw)
	ERBB2/HER2 activating mutations (SNVs and exon 20 insertions)	ENHERTU® (famtrastuzumab deruxtecannxki)
	KRAS G12C	LUMAKRAS™ (sotorasib)

A negative result from a plasma specimen does not assure that the patient's tumor is negative for genomic findings. NSCLC patients who are negative for the biomarkers listed in Table 1 should be reflexed to tissue biopsy testing for Table 1 biomarkers using an FDA approved tumor tissue test, if feasible.

*The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained.

Additionally, the test is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with any solid malignant neoplasms. The test is for use with patients previously diagnosed with cancer and in conjunction with other laboratory and clinical findings.

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

Guardant360 CDx is a single-site assay performed at Guardant Health, Inc.

Manufacturer	Guardant Health, Inc.
Number	P200010/S008
Filing Date	04/13/2022
Approval Date	08/11/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (17 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	120
Total Elapsed Days	120

Oncomine Dx Target Test

The Oncomine™ Dx Target Test is a qualitative in vitro diagnostic test that uses targeted high throughput, parallel-sequencing technology to detect single nucleotide variants (SNVs), insertions, and deletions in 23 genes from DNA and fusions in ROS1 and in RET from RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor samples from patients with non-small cell lung cancer (NSCLC), IDH1 SNVs from FFPE tumor tissue samples from patients with cholangiocarcinoma (CC), RET SNVs, multi-nucleotide variants (MNVs), and deletions from DNA isolated from FFPE tumor tissue samples from patients with medullary thyroid cancer (MTC), and RET fusions from RNA isolated from FFPE tumor tissue samples from patients with thyroid cancer (TC), using the Ion PGM™ Dx System.

The test is indicated as a companion diagnostic to aid in selecting NSCLC, CC, MTC, and TC patients for treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. List of Variants for Therapeutic Use

Tissue Type	Gene	Variant	Targeted Therapy
NSCLC	*BRAF*	*BRAF* V600E mutation	TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	EGFR	*EGFR* L858R mutation, *EGFR exon* 19 deletions	IRESSA® (gefitinib)
	EGFR	*EGFR* exon 20 insertions	EXKIVITY™ (mobocertinib)
			RYBREVANT™ (amivantamab-vmjw)

NSCLC	*ERBB2/HER2*	*ERBB2/HER2* activating mutations (SNVs and exon 20 insertions)	ENHERTU® (famtrastuzumab deruxtecannxki)
	RET	*RET* fusions	GAVRETO™ (pralsetinib) RETEVMO® (selpercatinib)
	ROS1	*ROS1* fusions	XALKORI® (crizotinib)
CC	*IDH1*	*IDH1 R132C, IDH1 R132G, IDH1 R132H IDH1 R132L,* and *IDH1 R132S* mutations	TIBSOVO® (ivosidenib)
MTC	*RET*	*RET* mutations (SNVs, MNVs, and deletions)	RETEVMO® (selpercatinib)
TC	*RET*	*RET* fusions	RETEVMO® (selpercatinib)

Safe and effective use has not been established for selecting therapies using this device for the variants other than those in **Table 1**.

Results other than those listed in **Table 1** are indicated for use only in patients who have already been considered for all appropriate therapies (including those listed in **Table 1**). Analytical performance using NSCLC specimens has been established for the variants listed in **Table 2**.

Table 2. List of Variants with Established Analytical Performance Only

Gene	Variant ID/Type	Amino Acid Change	Nucleotide Change
KRAS	COSM512	p.Gly12Phe	c.34_35delGGinsTT
KRAS	COSM516	p.Gly12Cys	c.34G>T
MET	COSM707	p.Thr1010Ile	c.3029C>T
PIK3CA	COSM754	p.Asn345Lys	c.1035T>A

The test is not indicated to be used for standalone diagnostic purposes, screening, monitoring, risk assessment, or prognosis.

Manufacturer	Life Technologies Corporation
Number	P160045/S031
Filing Date	09/24/2021
Approval Date	09/21/2022
Youngest Suggested Pediatric Subpopulation	Adolescents
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180

Total Elapsed Days	362

PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody

PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY antiHER2 (4B5) antibody) is a rabbit monoclonal antibody intended for laboratory use for the semi-quantitative detection of HER2 antigen by immunohistochemistry (IHC), in sections of formalin-fixed, paraffin-embedded normal and neoplastic breast tissue using the ultraView Universal DAB Detection Kit on a BenchMark ULTRA instrument.

This IHC device is indicated for identifying breast cancer patients who are eligible for treatment with Herceptin® (IHC 3+ or IHC 2+/ISH amplified), KADCYLA® (IHC 3+ or IHC 2+/ISH amplified) or ENHERTU® (IHC 1+ or IHC 2+/ISH non-amplified).

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
This antibody is intended for in vitro diagnostic (IVD) use.

Manufacturer	Ventana Medical Systems, Inc.
Number	P990081/S047
Filing Date	05/27/2022
Approval Date	09/30/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	126
Total Elapsed Days	126

EVO/EVO+ VISIAN Implantable Collamer Lens

(EVO/EVO+ Sphere Lenses)
The EVO ICL lens is indicated for use in patients 21-45 years of age:

1. for the correction of myopia with spherical equivalent ranging from -3.0 D to ≤ -15.0 D with less than or equal to 2.5 D of astigmatism at the spectacle plane;
2. for the reduction of myopia ranging from greater than -15.0 D to -20.0 D with less than or equal to 2.5 D of astigmatism at the spectacle plane;
3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens, and a stable refractive history (within 0.5 D for 1 year prior to implantation).
4. The ICL lens is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

(EVO/EVO+ Toric Lenses)
The EVO TICL lens is indicated for use in patients 21-45 years of age:

1. for the correction of myopic astigmatism with spherical equivalent ranging from -3.0 D to ≤ -15.0 D (in the spectacle plane) with cylinder (spectacle plane) of 1.0 D to 4.0 D.
2. for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0 D to -20.0 D (in the spectacle plane) with cylinder (spectacle plane) 1.0 D to 4.0 D.
3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5 D for both spherical equivalent and cylinder for 1 year prior to implantation).
4. The TICL lens is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.

Manufacturer	STAAR Surgical Company
Number	P030016/S035
Filing Date	02/05/2019
Approval Date	03/25/2022
Youngest Suggested Pediatric Subpopulation	Adolecsents (21 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	516
Total Elapsed Days	1144

CBER Device Information

Alinity m HIV-1; Alinity m System

The Alinity m HIV-1 assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) RNA on the automated Alinity m System for confirmation of HIV-1 infection or for monitoring HIV-1 infected individuals. The Alinity m HIV-1 assay is intended for use in the clinical management of HIV-1 infected individuals in conjunction with clinical presentation and other laboratory markers.

The Alinity m HIV-1 assay is intended for use to monitor disease prognosis by measuring baseline plasma HIV-1 RNA level and to assess response to antiretroviral treatment by measuring changes in plasma HIV-1 RNA levels. Performance for quantitative monitoring is not established with serum specimens.

The Alinity m HIV-1 assay is also intended for use as a supplemental test to confirm HIV-1 infection in individuals who have reactive results with HIV immunoassays.

Performance for supplemental use is established with both plasma and serum specimens.

The results from the Alinity m HIV-1 assay must be interpreted within the context of all relevant clinical and laboratory findings.

This device is not intended for use as a first line diagnostic test or for screening donors of blood, blood products, or human cells or tissues, or cellular and tissue-based products (HCT/Ps).

Manufacturer	Abbott Molecular Inc.
Number	BP200455-7
Filing Date	12/27/2021
Approval Date	07/08/2022
Youngest Suggested Pediatric Subpopulation	Neonates
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	123
Total Elapsed Days	193

B. FY 2023 Approvals of, and Review Times for, PMA and HDEs for Devices Indicated for Use in Pediatric Populations

FY 2023

CDRH Device Information

Avive AED, Avive AED Pad Cartridge, Avive AED Training Cartridge, Avive USB Charging Cable, Avive USB Power Adaptor

The Avive Automated External Defibrillator (AED) is intended for emergency treatment of individuals who are exhibiting symptoms of cardiac arrest. A person in cardiac arrest:

- Is unresponsive; and
- Is not breathing normally.

The Avive AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock to treat ventricular fibrillation or pulseless ventricular tachycardia.

The Avive AED is indicated for adult and pediatric patients over 1 years of age. When a patient is less than 8 years old, or weighs less than 55 lbs., the Avive AED should be used in Child Mode. Otherwise, the Avive AED should be used in Adult Mode. Therapy should not be delayed in order to determine exact age and/or weight.

Manufacturer	Avive Solutions, Inc
Number	P210015
Filing Date	04/06/2021
Approval Date	10/31/2022
Youngest Suggested Pediatric Subpopulation	Infants (1 year and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	573

VENTANA FOLR1 (FOLR-2.1) RxDx Assay

VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha (FOLR1) protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube or primary peritoneal cancer tissue specimens by light microscopy. This assay is for use with OptiView DAB IHC Detection Kit for staining on a BenchMark ULTRA instrument.
FOLR1 expression clinical cut-off is ≥ 75% viable tumor cells (TC) with membrane staining at moderate and/or strong intensity levels.
This assay is indicated as an aid in identifying patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who may be eligible for treatment with ELAHERE (mirvetuximab soravtansine).
Test results of the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.
This product is intended for in vitro diagnostic (IVD) use.

Manufacturer	Ventana Medical Systems Inc.
Number	P220006
Filing Date	04/25/2022
Approval Date	11/14/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	143
Total Elapsed Days	203

QDOT MICRO™ System

The QDOT MICRO™ System is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a compatible radiofrequency generator, for the treatment of:

- Type I atrial flutter in patients age 18 or older

- Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.

The Biosense Webster QDOT MICRO™ Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with the CARTO® 3 Navigation System.

Manufacturer	Biosense Webster, Inc.
Number	P210027
Filing Date	08/11/2021
Approval Date	11/23/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	192
Total Elapsed Days	469

Agilent Resolution ctDx FIRST

The Agilent Resolution ctDx FIRST assay is a qualitative next generation sequencingbased, in vitro diagnostic test that uses targeted hybrid-capture sequencing technology to detect and report single nucleotide variants (SNVs) and deletions in two genes. The Agilent Resolution ctDx FIRST assay utilizes circulating cell-free DNA (cfDNA) isolated from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended as a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) who may benefit from treatment with the targeted therapy listed in Table 1, in accordance with the approved therapeutic labeling.

Table 1. Companion Diagnostic Indication

Indication	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	*KRAS* G12C	KRAZATI™ (adagrasib)

A negative result from a plasma specimen does not assure that the patient's tumor is negative for genomic findings. Patients with NSCLC who are negative for the biomarker listed in Table 1 should be reflexed to tissue biopsy testing for Table 1 biomarker using an FDA-approved tumor tissue test, if feasible.

Additionally, the test is intended to provide tumor mutation profiling for SNVs and deletions in the EGFR gene for use by qualified health care professionals in accordance with professional guidelines in oncology for patients with NSCLC. The test is for use with patients previously diagnosed with NSCLC and in conjunction with other laboratory and clinical findings.

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

The Agilent Resolution ctDx FIRST assay is a single-site assay performed at Resolution Bioscience, Inc.

Manufacturer	Resolution Bioscience, Inc.
Number	P210040
Filing Date	01/10/2022
Approval Date	12/12/2022
Youngest Suggested Pediatric Subpopulation	Adolescents (17 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	336

FoundationOne® Liquid CDx (F1 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 substitutions, insertions and deletions (indels) in 311 genes, rearrangements in eight (8) genes, and copy number alterations in three (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 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)
	EGFR Exon 19 deletions and *EGFR* Exon 21 L858R alteration	*EGFR* tyrosine kinase inhibitors approved by FDA*
	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)

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)

*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-approvedcompanion-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/S004
Filing Date	04/13/2022
Approval Date	12/22/2022
Youngest Suggested Pediatric Subpopulation	Adolescents • 12 years and older for NTRK1/2/3 fusion • 18 years and older for ROS1 fusion
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	197
Total Elapsed Days	253

Prodigy, Proclaim, and Proclaim XR Spinal Cord Stimulation (SCS) Systems

This spinal cord stimulation (SCS) systems 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, and diabetic peripheral neuropathy of the lower extremities.

Manufacturer	Abbott Medical
Number	P010032/S189
Filing Date	07/15/2022
Approval Date	01/24/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	185
Total Elapsed Days	193

Guardant360® CDx

Guardant360® CDx is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360 CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the therapies listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. Companion Diagnostic Indications

Indication	Biomarker	Therapy
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions, L858R, and T790M*	TAGRISSO® (osimertinib)
	EGFR exon 20 insertions	RYBREVANT® (amivantamab-vmjw)
	ERBB2/HER2 activating mutations (SNVs and exon 20 insertions)	ENHERTU® (fam-trastuzumab deruxtecan-nxki)
	KRAS G12C	LUMAKRAS™ (sotorasib)
Breast cancer	*ESR1* missense mutations between codons 310 and 547	ORSERDU™ (elacestrant)

A negative result from a plasma specimen does not assure that the patient's tumor is negative for genomic findings. Patients who are negative for the biomarkers listed in

Table 1 should be reflexed to tissue biopsy testing for Table 1 biomarkers using an FDAapproved tumor tissue test, if feasible.

*The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained.

Additionally, the test is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with any solid malignant neoplasms. The test is for use with patients previously diagnosed with cancer and in conjunction with other laboratory and clinical findings.

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

Guardant360 CDx is a single-site assay performed at Guardant Health, Inc.

Manufacturer	Guardant Health, Inc.
Number	P200010/S010
Filing Date	06/21/2022
Approval Date	01/27/2023
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	220

VENTANA PD-L1 (SP263) Assay

VENTANA PD-L1 (SP263) Assay is a qualitative immunohistochemistry assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the programmed death ligand-1 (PD-L1) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue specimens by light microscopy. The VENTANA PD-L1 (SP263) Assay is used with the OptiView DAB IHC Detection Kit for staining on the BenchMark ULTRA instrument.

PD-L1 protein expression in NSCLC is determined by the percentage of tumor cells (%TC) with any membrane staining above background.

VENTANA PD-L1 (SP263) assay is indicated as an aid in identifying patients eligible for treatment with the therapy listed in Table 1 for the indication and PD-L1 status in accordance with the approved therapeutic product labeling.

Table 1. VENTANA PD-L1 (SP263) Assay Companion Diagnostic Indication

Indication for Use	PD-L1 Cut-off	Therapy
NSCLC	≥ 1% TC	TECENTRIQ (atezolizumab)
NSCLC	≥ 50% TC	LIBTAYO (cemiplimab-rwlc)

Results of the VENTANA PD-L1 (SP263) Assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This product is intended for in vitro diagnostic (IVD) use.

Manufacturer	Ventana Medical Systems, Inc.
Number	P160046/S013
Filing Date	04/21/2022
Approval Date	03/01/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	193
Total Elapsed Days	314

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 and treatment planning of demineralization associated with caries lesions.

Manufacturer	CALCIVIS Limited
Number	P170029
Filing Date	10/02/2017
Approval Date	03/07/2023
Youngest Suggested Pediatric Subpopulation	Children (6 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	364
Total Elapsed Days	1982

Relay®Pro Thoracic Stent-Graft System

The Relay®Pro Thoracic Stent-Graft System is indicated for the endovascular repair of all lesions of the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic neck diameter in the range of:
    - 20 – 42 mm for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers and dissections
    - 19 – 42 mm for traumatic aortic injuries;
- Proximal landing zone (non-aneurysmal proximal aortic neck lengths for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers or non-dissected length of aorta proximal to the primary entry tear for dissections and length of aorta proximal to the tear for traumatic aortic injuries) of:
    - 15 mm for the 22 – 28 mm device diameters (Bare Stent Configuration)
    - 20 mm for the 30 – 38 mm device diameters (Bare Stent Configuration)
    - 25 mm for the 40 – 46 mm device diameters (Bare Stent Configuration)
    - 25 mm for the 22 – 38 mm device diameters (Non-Bare Stent Configuration)
    - 30 mm for the 40 – 46 mm device diameters (Non-Bare Stent Configuration)
- Non-aneurysmal distal aortic neck lengths for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers of:
    - 25 mm for the 24 – 38 mm device diameters
    - 30 mm for the 40 – 46 mm device diameters
- Non-aneurysmal distal landing zone of 20 mm for traumatic aortic injuries (22 mm – 46 mm device diameters) and dissections (24 mm – 46 mm device diameters)

The Relay®Pro Thoracic Stent-Graft System (NBS configuration) is indicated for the endovascular distal extension of the Thoraflex Hybrid device.

Manufacturer	Bolton Medical, Inc.
Number	P200045/S002
Filing Date	05/16/2022
Approval Date	03/07/2023
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	295

Inspire® Upper Airway Stimulation (UAS)

Inspire Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

(1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or

(2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Inspire UAS is also indicated for use in patients between the ages of 18 and 21 with moderate to severe OSA (15≤AHI≤65), and pediatric patients ages 13 to 18 years with Down syndrome and severe OSA (10≤AHI≤50) who:

- Do not have complete concentric collapse at the soft palate level
- Are contraindicated for or not effectively treated by adenotonsillectomy
- Have been confirmed to fail, or cannot tolerate PAP therapy despite attempts to improve compliance
- Have followed standard of care in considering all other alternative/adjunct therapies

Manufacturer	Inspire Medical Systems, Inc.
Number	P130008/S089
Filing Date	08/19/2022
Approval Date	03/20/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (13 years and older) • This supplement was submitted to add patients ages 13 to 18 years with Down syndrome and severe OSA (10≤AHI≤50).
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	180
Total Elapsed Days	213

Eversense® E3 Continuous Glucose Monitoring (CGM) System

The Eversense® E3 CGM System is intended for continually measuring glucose levels in adults (18 years and older) with diabetes for up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.
The system is intended to:

- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The system is intended for single patient use.

Manufacturer	Senseonics, Incorporated
Number	P160048/S021
Filing Date	09/30/2022
Approval Date	03/29/2023
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

NeuRx® Diaphragm Pacing System (NeuRx DPS®)

The NeuRx DPS® is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but who lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. For use only in patients 18 years of age or older.

Manufacturer	Synapse Biomedical, Inc.
Number	P200018
Filing Date	03/12/2020
Approval Date	03/31/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	194
Total Elapsed Days	1114

Lava™ Liquid Embolic System (Lava LES)

The Lava LES is indicated for embolization of arterial hemorrhage in the peripheral vasculature.

Manufacturer	BlackSwan Vascular, Inc.
Number	P220020
Filing Date	10/06/2022
Approval Date	04/04/2023
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

MiniMed 780G System

The MiniMed 780G system is indicated for use with either the Guardian Sensor (3)/Guardian Link (3) Transmitter, or with the Guardian 4 sensor/Guardian 4 transmitter Indications for use for the MiniMed 780G system are provided for each of the two system configurations separately:

MiniMed 780G System for use with Guardian Sensor (3)/Guardian Link (3) Transmitter

MiniMed 780G System
The MiniMed 780G system is intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard (SG) technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The MiniMed 780G system consists of the following devices:

- MiniMed 780G insulin pump
- Guardian Link (3) transmitter
- Guardian Sensor (3)
- One-press serter
- Accu-Chek™ Guide Link blood glucose meter
- Accu-Chek™ Guide Test Strips

The system requires a prescription from a healthcare professional.
Guardian Sensor (3)

The Guardian Sensor (3) is intended for use with the MiniMed 780G system, MiniMed 770G system, MiniMed 670G system, MiniMed 630G system, and Guardian Connect system to continuously monitor glucose levels in persons with diabetes.

The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for seven days of continuous use.

The Guardian Sensor (3) is not intended to be used directly to make therapy adjustments while the MiniMed 780G system is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian Sensor (3).

The Guardian Sensor (3) has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table:

System	Approved Age	Sensor Insertion Site
MiniMed 780G system	7- 13 14 and older	Abdomen and Buttocks Abdomen and Arm
MiniMed 770G system	2-13 14 and older	Abdomen and Buttocks Abdomen and Arm
MiniMed 670G system	7-13 14 and older	Abdomen and Buttocks Abdomen and Arm
MiniMed 630G system	14 and older	Abdomen and Arm
Guardian Connect system	14 and older	Abdomen and Arm

One-press Serter
The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use.

Guardian Link (3) Transmitter
The Guardian Link (3) Transmitter is intended for use with the MiniMed 780G system. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 780G insulin pump. The transmitter is intended for single-patient multi-use.

Accu-Chek™ Guide Link Blood Glucose Monitoring System
The Accu-Chek™ Guide Link Blood Glucose Monitoring System is comprised of the Accu- Chek™ Guide Link meter and the Accu-Chek™ Guide test strips.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended for invitro diagnostic single-patient use by people with diabetes.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed 780G system and MiniMed 770G system with Bluetooth wireless technology through the use of Bluetooth low energy communication.

MiniMed 780G System for use with Guardian 4 Sensor/Guardian 4 Transmitter

MiniMed 780G System
The MiniMed 780G system is intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard (SG) technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The MiniMed 780G system consists of the following devices:
- MiniMed 780G insulin pump
- Guardian 4 transmitter
- Guardian 4 sensor
- One-press serter
- Accu-Chek™ Guide Link blood glucose meter
- Accu-Chek™ Guide Test Strips

The system requires a prescription from a healthcare professional.

Guardian 4 Sensor
The Guardian 4 Sensor is intended for use with the MiniMed 780G system and the Guardian 4 transmitter to continuously monitor glucose levels for the management of diabetes.

The sensor is intended for single use and requires a prescription. The Guardian 4 sensor is indicated for up to seven days of continuous use.

The Guardian 4 sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian 4 sensor.

The Guardian 4 sensor has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table.

System	Age	Sensor Insertion Site
MiniMed 780G system	7 years and older	Arm

One-press Serter
The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use.

Guardian 4 Transmitter
The Guardian 4 transmitter is intended for use with the MiniMed 780G system and Guardian 4 sensor to monitor glucose levels for the management of diabetes.

Accu-Chek™ Guide Link Blood Glucose Monitoring System
The Accu-Chek™ Guide Link Blood Glucose Monitoring system is comprised of the Accu- Chek™ Guide Link meter and the Accu-Chek Guide test strips.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended for invitro diagnostic single-patient use by people with diabetes.

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Accu-Chek™ Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed 780G system and MiniMed 770G system with Bluetooth wireless technology through the use of Bluetooth low energy communication.

Manufacturer	Medtronic MiniMed, Inc.
Number	P160017/S091
Filing Date	05/10/2021

Approval Date	04/21/2023
Youngest Suggested Pediatric Subpopulation	Children (7 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	607
Total Elapsed Days	711

Precision7™; Precision7™ for Astigmatism; Precision7™ Multifocal; Precision7™ Multifocal Toric (serafilcon A) Soft Contact Lenses

Precision7™ (serafilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic and aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

Precision7™ for Astigmatism (serafilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have up to 6.00 diopters (D) of astigmatism.

Precision7™ Multifocal (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Precision7™ Multifocal Toric (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to 6.00 diopters (D) of astigmatism.

The lenses are to be prescribed for extended wear for up to 6 continuous nights with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.

Manufacturer	Alcon Laboratories, Inc.
Number	P220007
Filing Date	07/07/2022
Approval Date	04/25/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No

FDA Days	192
Total Elapsed Days	292

xT CDx

xT CDx is a qualitative Next Generation Sequencing (NGS)-based in vitro diagnostic device intended for use in the detection of substitutions (single nucleotide variants (SNVs) and multi-nucleotide variants (MNVs)) and insertion and deletion alterations (INDELs) in 648 genes, as well as microsatellite instability (MSI) status, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens, and DNA isolated from matched normal blood or saliva specimens, from previously diagnosed cancer patients with solid malignant neoplasms.

The test is intended as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table in accordance with the approved therapeutic product labeling.

Additionally, xT 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 previously diagnosed solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product.

xT CDx is a single-site assay performed at Tempus Labs, Inc., Chicago, IL.

Companion diagnostic indications

Tumor Type	Biomarker(s) Detected	Therapy
Colorectal cancer (CRC)	KRAS wild type (absence of mutations in codons 12 or 13)	Erbitux (cetuximab)
Colorectal cancer (CRC)	KRAS wild type (absence of mutations in exons 2, 3, or 4) and NRAS wild type (absence of mutations in exons 2, 3, or 4)	Vectibix (panitumumab)

Manufacturer	Tempus Labs, Inc.
Number	P210011
Filing Date	03/23/2021
Approval Date	04/28/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	468
Total Elapsed Days	766

ADVIA Centaur® HBc Total 2 (HBcT2); ADVIA Centaur® HBc Total 2 Quality Control (HBcT2 QC); Atellica IM® HBc Total 2 (HBcT2); Atellica IM® HBc Total 2 Quality Control (HBcT2 QC)

The ADVIA Centaur® HBc Total 2 (HBcT2):
The ADVIA Centaur® HBc Total 2 (HBcT2) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA, lithium heparin, and sodium heparin) using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.

This assay can be used as an aid in the diagnosis of acute or chronic hepatitis B virus (HBV) infection, and in the determination of the clinical status of HBV-infected individuals in conjunction with other HBV serological markers, for the laboratory diagnosis of HBV disease associated with HBV infection. This assay can also be used as an aid in the differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.

This assay is not intended for screening donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps).

ADVIA Centaur® HBc Total 2 Quality Control (HBcT2 QC)
The ADVIA Centaur® HBc Total 2 (HBcT2) Quality Control material is for in vitro diagnostic use for monitoring the performance of the ADVIA Centaur HBc Total 2 (HBcT2) assay using the ADVIA Centaur systems.
The performance of the ADVIA Centaur HBcT2 Quality Control material has not been with any other anti-HBc Total assay.

The ADVIA Centaur® HBc Total 2 (HBcT2):
The ADVIA Centaur® HBc Total 2 (HBcT2) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA, lithium heparin, and sodium heparin) using the ADVIA Centaur® CP systems.

This assay can be used as an aid in the diagnosis of acute or chronic hepatitis B virus (HBV) infection, and in the determination of the clinical status of HBV-infected individuals in conjunction with other HBV serological markers, for the laboratory diagnosis of HBV disease associated with HBV infection. This assay can also be used as an aid in the differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.

This assay is not intended for screening donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps).

ADVIA Centaur® HBc Total 2 Quality Control (HBcT2 QC)
The ADVIA Centaur® HBc Total 2 (HBcT2) Quality Control material is for in vitro diagnostic use for monitoring the performance of the ADVIA Centaur HBc Total 2 (HBcT2) assay using the ADVIA Centaur systems.

The performance of the ADVIA Centaur HBcT2 Quality Control material has not been with any other anti-HBc Total assay.

The Atellica IM HBc Total 2 (HBcT2):
The ADVIA Centaur® HBc Total 2 (HBcT2) assay is an in vitro diagnostic immunoassay for use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human pediatric (2-21 years old) and adult serum and plasma (EDTA, lithium heparin, and sodium heparin) using the Atellica IM Analyzer.

This assay can be used as an aid in the diagnosis of acute or chronic hepatitis B virus (HBV) infection, and in the determination of the clinical status of HBV-infected individuals in conjunction with other HBV serological markers, for the laboratory diagnosis of HBV disease associated with HBV infection. This assay can also be used as an aid in the differential diagnosis in individuals displaying signs and symptoms of hepatitis in whom etiology is unknown.

This assay is not intended for screening donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Atellica IM® HBc Total 2 Quality Control (HBcT2 QC)
The Atellica IM HBc Total 2 (HBcT2) Quality Control material is for in vitro diagnostic use for monitoring the performance of the Atellica IM HBc Total 2 (HBcT2) assay using the Atellica IM systems.

The performance of the Atellica IM HBcT2 Quality Control material has not been with any other anti-HBc Total assay.

Manufacturer	Siemens Healthcare Diagnostics, Inc.
Number	P210019/S002
Filing Date	10/31/2022
Approval Date	04/28/2023
Youngest Suggested Pediatric Subpopulation	Children • This supplement was submitted to add human pediatric (2-21 years old).
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	179
Total Elapsed Days	179

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 substitutions, insertions and deletions (indels) in 311 genes, rearrangements in eight (8) genes, and copy number alterations in three (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 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)
	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)
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)

*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-approvedcompanion-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/S005
Filing Date	08/15/2022
Approval Date	05/03/2023
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	261

Prodigy, Proclaim XR, Proclaim Plus, and Externa Spinal Cord Stimulation (SCS) Systems

Abbott Medical spinal cord stimulation (SCS) systems are 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, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Manufacturer	Abbott Medical
Number	P010032/S191
Filing Date	09/02/2022
Approval Date	05/10/2023
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	250

REFLECT™ Scoliosis Correction System

The REFLECT™ Scoliosis Correction System is indicated for skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear.

Modifications from the HUD Designation

The indication for use statement has been modified from that granted for the HUD designation. The HUD designation was, “for treatment of skeletally immature patients (Risser<5) with a major Cobb angle ≥30°, who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, and who have failed bracing and/or are intolerant to bracing.” It was modified for the HDE approval as follows: removed Risser sign as a Risser score less than 5 is synonymous with skeletally immature patients; and, identified Cobb angle range to better reflect the study population. The resulting Indications for Use statement falls within the HUD designation.

Manufacturer	Globus Medical, Inc.
Number	H210002
Filing Date	08/12/2021
Approval Date	05/15/2023
Youngest Suggested Pediatric Subpopulation	Children (8 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	Not subject to user fees
FDA Days	289
Total Elapsed Days	641

Inspire Upper Airway Stimulation System

Inspire Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 100). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

(1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or

(2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Inspire UAS is also indicated for use in patients between the ages of 18 to 21 with moderate to severe OSA (15≤AHI≤100), and pediatric patients ages 13 to 18 years with Down syndrome and AHI greater than 10 and less than 50 who:

- Do not have complete concentric collapse at the soft palate level
- Are contraindicated for or not effectively treated by adenotonsillectomy
- Have been confirmed to fail, or cannot tolerate PAP therapy despite attempts to improve compliance
- Have followed standard of care in considering all other alternative/adjunct therapies

Manufacturer	Inspire Medical Systems, Inc.
Number	P130008/S090
Filing Date	10/19/2022
Approval Date	06/08/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older) • This supplement was submitted to add OSA patients, 18 years of age or older, with AHI ≤100.
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	180
Total Elapsed Days	232

FoundationOne® Liquid CDx (F1 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 substitutions, insertions and deletions (indels) in 311 genes, rearrangements in eight (8) genes, and copy number alterations in three (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 in accordance with the approved therapeutic product labeling.

Tumor Type	Biomarker(s) Detected	Therapy
Non-small cell lung cancer (NSCLC)	*ALK* Rearrangements	ALECENSA® (alectinib)
	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)
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 alteration	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-approvedcompanion-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/S010
Filing Date	11/22/2022
Approval Date	06/08/2023
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	198

HeartSync Multifunction Disposable Single-Use AED Defibrillator Pads

These are multifunction pads, and can be used with automatic or manual defibrillators for monitoring, pacing, cardioversion, as well as defibrillation. These indications are consistent with current AHA Guidelines.

For Automatic External Defibrillators:
(Compatible Model AEDs: Physio Control: LifePak-15, LifePak-20/20e, LifePak -1000; Zoll Medical: R-Series, X-Series; Cardiac Science: PowerHeart AED G3 Plus, PowerHeart AED G3 Pro).
When used with an external defibrillator, these electrode pads are for treating patients in cardiopulmonary arrest who are:

- Unconscious,
- Not breathing spontaneously
- Without circulation (without a pulse).

The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used on patients over 8 years of age or greater than 55 pounds. The pads are intended for short term use (less than 8 hours).
DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

For Manual Defibrillators:
Manual Defibrillators can be used for monitoring, pacing, cardioversion, as well as defibrillation.

When used for defibrillation, these electrode pads are for treating patients in cardiopulmonary arrest who are:

- Unconscious,

- Not breathing spontaneously
- Without circulation (without a pulse).

The pads are single use and intended to be used in conjunction with an external defibrillator to monitor and deliver defibrillation energy to the patient. The pads are used on patients greater than 10 kg or 22 pounds. The pads are intended for short term use (less than 24 hours).
DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

Manufacturer	Graphic Controls dba Nissha Medical Technologies/ Vermed/ Biomedical Innovations
Number	P200007
Filing Date	02/12/2020
Approval Date	06/23/2023
Youngest Suggested Pediatric Subpopulation	Children (8 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	177
Total Elapsed Days	1227

AAV5 DetectCDx

The AAV5 Total Antibody Assay for ROCTAVIAN (valoctocogene roxaparvovec-rvox) Eligibility in Hemophilia A (“AAV5 TAb Assay”), or AAV5 DetectCDx, is a qualitative in vitro diagnostic test by electrochemiluminescence intended for detection of antibodies in human plasma collected in 3.2% sodium citrate that bind to the adeno-associated virus serotype 5 (AAV5). The AAV5 TAb Assay is indicated as an aid in the selection of adult hemophilia A patients for whom ROCTAVIAN treatment is being considered. Patients that are anti-AAV5 antibody positive (result of Detected) are not eligible for treatment with ROCTAVIAN; patients that are anti-AAV5 antibody negative (result of Not Detected) are eligible for treatment with ROCTAVIAN. This assay is for professional use and is a single-site assay performed at ARUP Laboratories.

Manufacturer	ARUP Laboratories
Number	P190033
Filing Date	12/23/2019
Approval Date	6/29/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	291
Total Elapsed Days	1284

therascreen® PDGFRA RGQ PCR Kit

The QIAGEN *therascreen*® PDGFRA RGQ PCR Kit is a real-time qualitative in vitro diagnostic assay for the detection of the D842V somatic mutation in the *PDGFRA* gene using genomic DNA extracted from Gastrointestinal Stromal Tumor (GIST) patient's formalin-fixed paraffin-embedded (FFPE) tumor tissue.

The therascreen PDGFRA RGQ PCR Kit is intended for use as a companion diagnostic test, to aid clinicians in identification of patients with GIST who may be eligible for treatment with AYVAKIT™ (avapritinib) based on a *PDGFRA* mutation detected result. FFPE tumor specimens are processed using the QIAamp® DSP DNA FFPE Tissue Kit for manual sample preparation and the Rotor-Gene® Q (RGQ) MDx instrument for automated amplification and detection.

Manufacturer	QIAGEN GmbH
Number	P210002
Filing Date	01/29/2021
Approval Date	06/29/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	578
Total Elapsed Days	881

CraniSeal Dural Sealant

The CraniSeal Dural Sealant is indicated for use in patients ≥ 18 years of age as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.

Manufacturer	Pramand, LLC
Number	P220014
Filing Date	09/27/2022
Approval Date	07/06/2023
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	282

PALMAZ MULLINS XDTM Pulmonary Stent

The PALMAZ MULLINS XD Pulmonary Stent is indicated for the non-emergency treatment of pulmonary artery stenosis in pediatric patients who are at least 10kg in weight with two ventricle anatomy.

Manufacturer	Cordis US Corp.
Number	P220004
Filing Date	04/12/2022
Approval Date	07/21/2023
Youngest Suggested Pediatric Subpopulation	Infants (10kg and above)
Exempt from User Fees Because Intended Solely for Pediatric Use?	Yes
FDA Days	191
Total Elapsed Days	465

CRCdx® RAS Mutation Detection Kit

The CRCdx RAS Mutation Detection Kit is a qualitative real-time PCR in vitro diagnostic test intended for the detection of 35 variants of KRAS and NRAS exon 2, 3, 4 somatic mutations in genomic DNA extracted from formalin-fixed, paraffinembedded (FFPE) colorectal cancer (CRC) tissue samples. The test is intended as a companion diagnostic (CDx) to aid in the identification of colorectal cancer (CRC) patients who may benefit from treatment with Vectibix (panitumumab) based on a no mutation detected test result in accordance with the approved therapeutic product labeling.

The CRCdx RAS assay is performed on the QuantStudio Dx real-time PCR instrument (QSDx) for testing analyses and data collection. The data are analyzed by EntroGen's PCR Analysis Software (EPAS) for result interpretation.

Manufacturer	EntroGen, Inc.
Number	P220005
Filing Date	04/20/2022
Approval Date	09/29/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	192
Total Elapsed Days	527

CBER Device Information

RECELL® Autologous Cell Harvesting Device (Model Number: AVRL0102)

The RECELL Autologous Cell Harvesting Device is indicated for repigmentation of stable depigmented vitiligo lesions in patients 18 years of age and older. The RECELL Device is intended for use by an appropriately licensed and trained healthcare professional at the patient's point-of-care for the safe and rapid preparation of Spray-On Skin Cells from a small sample of a patient's own skin. The suspension of Spray-On

Skin Cells is suitable for application to skin resurfaced by an ablative laser. A portion of the suspension of Spray-On Skin Cells may also be applied to the donor site.

Manufacturer	AVITA Medical Americas, LLC.
Number	BP220799
Filing Date	12/16/2022
Approval Date	06/16/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (18 years and older)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	179
Total Elapsed Days	179

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	BP170122/502
Filing Date	12/09/2022
Approval Date	06/07/2023
Youngest Suggested Pediatric Subpopulation	Adolescents (15 years and older) • New indication added for full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing tissue infection) or resection (e.g., skin cancer)
Exempt from User Fees Because Intended Solely for Pediatric Use?	No
FDA Days	179
Total Elapsed Days	182

Appendix B: PMA and HDE Application Approvals for Devices with a Pediatric Indication from FY 2008 to FY 2023 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 2023 (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%)

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

Table 2. PMA and HDE Application Approvals Indicated for Pediatric Subpopulations by Age from FY 2013 to FY 2023.

Pediatric Subpopulation	PMA	HDE	Total
FY 2013			
Neonates (birth - 28 days)	**0**	**0**	**0**
Infants (29 days to <2 years)	**0**	**0**	**0**
Children (2 - 12 years)	**0**	**0**	**0**
Adolescents (12 - 21 years)	**9**	**0**	**9**
FY 2014			
Neonates (birth - 28 days)	**1**	**1**	**2**
Infants (29 days to <2 years)	**0**	**0**	**0**
Children (2 - 12 years)	**1**	**1**	**2**
Adolescents (12 - 21 years)	**4**	**0**	**4**
FY 2015			
Neonates (birth - 28 days)	**1**	**0**	**1**
Infants (29 days to <2 years)	**1**	**0**	**1**
Children (2 - 12 years)	**4**	**0**	**4**
Adolescents (12 - 21 years)	**7**	**1**	**8**
FY 2016			
Neonates (birth - 28 days)	**0**	**1**	**1**
Infants (29 days to <2 years)	**0**	**0**	**0**
Children (2 - 12 years)	**2**	**0**	**2**
Adolescents (12 - 21 years)	**11**	**0**	**11**
FY 2017			
Neonates (birth - 28 days)	**2**	**1**	**3**
Infants (29 days to <2 years)	**1**	**0**	**1**
Children (2 - 12 years)	**8**	**0**	**8**
Adolescents (12 - 21 years)	**6**	**1**	**7**
FY 2018			
Neonates (birth - 28 days)	**1**	**0**	**1**
Infants (29 days to <2 years)	**3**	**0**	**3**
Children (2 - 12 years)	**4**	**1**	**5**
Adolescents (12 - 21 years)	**13**	**0**	**13**
FY 2019			
Neonates (birth - 28 days)	**0**	**0**	**0**
Infants (29 days to <2 years)	**4**	**0**	**4**
Children (2 - 12 years)	**1**	**1**	**2**
Adolescents (12 - 21 years)	**3**	**1**	**4**
FY 2020			
Neonates (birth - 28 days)	**3**	**0**	**3**

Infants (29 days to <2 years)	**4**	**0**	**4**
Children (2 - 12 years)	**13**	**0**	**13**
Adolescents (12 - 21 years)	**6**	**0**	**6**
FY 2021			
Neonates (birth - 28 days)	**2**	**0**	**2**
Infants (29 days to <2 years)	**2**	**1**	**3**
Children (2 - 12 years)	**5**	**0**	**5**
Adolescents (12 - 21 years)	**5**	**0**	**5**
FY 2022			
Neonates (birth - 28 days)	**2**	**1**	**3**
Infants (29 days to <2 years)	**0**	**0**	**0**
Children (2 - 12 years)	**2**	**0**	**2**
Adolescents (12 - 21 years)	**15**	**0**	**15**
FY 2023			
Neonates (birth - 28 days)	**0**	**0**	**0**
Infants (29 days to <2 years)	**2**	**0**	**2**
Children (2 - 12 years)	**4**	**1**	**5**
Adolescents (12 - 21 years)	**24**	**0**	**24**

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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