Breakthrough Devices Program

The FDA seeks input on the draft guidance "Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care (/regulatory-information/search-fda-guidance-documents/select-updates-breakthrough-devices-program-guidance-reducing-disparities-health-and-health-care)." Submit comments before December 20, 2022.

On this page:

- What is the Breakthrough Devices Program?
- What are the benefits of the Breakthrough Devices Program?
- Is my device eligible?
- When to request a Breakthrough Devices Designation
- How to request a Breakthrough Devices Designation
- What to include in a request for a Breakthrough Devices Designation
- When will I find out if my device received a Breakthrough Device Designation
- What a sponsor can expect from the FDA if the Breakthrough Devices Designation is granted
- Are there related programs designed to expedite the availability of certain devices that might apply to my device?
- Will FDA announce when a device has been granted Breakthrough Device designation?
- Breakthrough Devices Program Metrics
- CDRH and CBER Breakthrough Device Marketing Authorizations
- Guidances related to Breakthrough Devices Program
- Contact Us

What is the Breakthrough Devices Program?

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products (/combination-products/about-combination-products) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

The Breakthrough Devices Program replaces the Expedited Access Pathway and Priority Review for medical devices. The FDA considers devices granted designation under the Expedited Access Pathway to be part of the Breakthrough Devices Program.

What are the benefits of the Breakthrough Devices Program?

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. Learn more about the Breakthrough Devices Program principles and features in Sections II and IV of the Breakthrough Devices Program final guidance (/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program).

Is my device eligible?

Devices subject to premarket approval applications (PMAs), premarket notification (510(k)) or requests for De Novo designation are eligible for breakthrough device designation if both of the following criteria are met:

Criteria	Description	Refer to Guidance
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions	Section III.B.1
Second Criterion	The device also meets **at least one** of the following:	
	a. Represents Breakthrough Technology	Section III.B.2.a
	b. No Approved or Cleared Alternatives Exist	Section III.B.2.b
	c. Offers Significant Advantages over Existing Approved or Cleared Alternatives	Section III.B.2.c
	d. Device Availability is in the Best Interest of Patients	Section III.B.2.d

When to request a Breakthrough Devices Designation

You can send a Breakthrough Designation request for your device at any time prior to sending your marketing submission (for example, premarket approval (PMA), premarket notification (510(k)), or De Novo classification request).

How to request a Breakthrough Devices Designation

You can request the Breakthrough Device designation by submitting a "Designation Request for Breakthrough Device" Q-Submission. Your designation request should be the only request in the Q-Submission. If you are pursuing the Breakthrough Device designation while you have other requests for feedback pending, you may want to send the requests for feedback after the FDA makes a designation decision because the designation may affect the feedback that the FDA provides on your other requests. The procedures for submitting a Q-

Submission are outlined in the guidance Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program).

The FDA may find devices that could be good candidates for the Breakthrough Devices Program and recommend that sponsors of such devices consider applying to the program.

What to include in a request for a Breakthrough Devices Designation

The FDA recommends that your designation request include information to describe the device, the proposed indication for use, regulatory history, how your device meets the statutory criteria for a Breakthrough Device, and what type of marketing submission you plan to submit to the FDA for your device. Learn more about what to include in your request in Appendix 1 of the Breakthrough Devices Program final guidance (/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program).

When will I find out if my device received Breakthrough Device Designation

The FDA intends to request any other information needed to inform the Breakthrough Device designation decision within 30 days of receiving your request. You can expect to receive a letter communicating the FDA's decision to grant or deny the Breakthrough Device designation request within 60 calendar days of the FDA receiving your request.

It is helpful when a sponsor is available and responsive to the FDA's requests throughout the review timeline. If the FDA does not receive the other information needed to decide on a designation request promptly, it may result in denial of the Breakthrough Device designation request.

What a sponsor can expect from FDA if Breakthrough Designation is Granted

If your device is granted the Breakthrough Device Designation, you can choose to interact with the FDA to obtain feedback on your device development through a variety of options including sprint discussions, request for discussion on a data development plan, and request for clinical protocol agreement. Learn more about these options in Section IV of the Breakthrough Devices Program guidance (/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program).

You will also receive prioritized review on future regulatory submissions, including Q-Submissions, Investigational Device Exemption (IDE) applications, and marketing submissions.

Are there related programs designed to expedite the availability of certain devices that might apply to my device?

If your device is not eligible for a Breakthrough Device Designation because it is not intended for the treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition, you may consider whether or not it would be a candidate for the Safer Technologies Program (/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices).

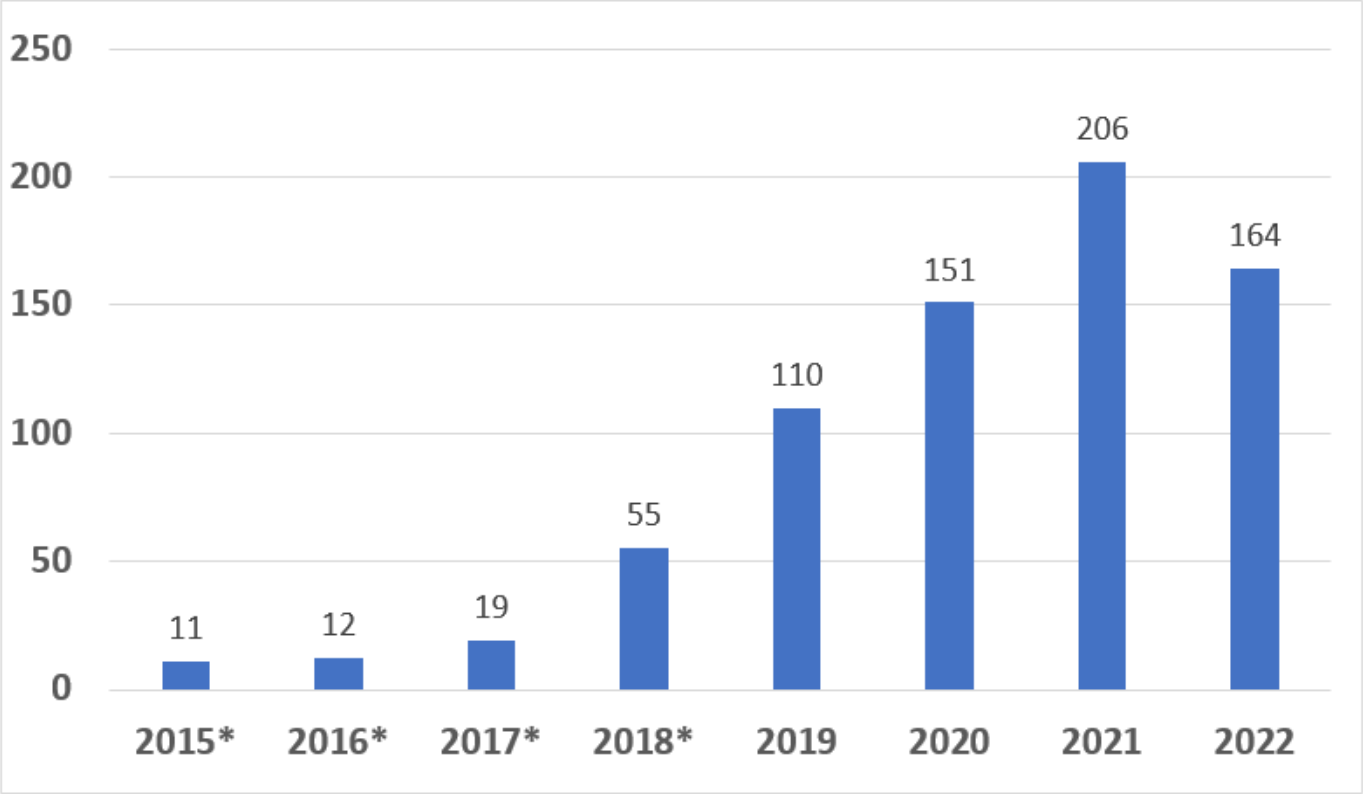
Will the FDA announce when a device has been granted Breakthrough Device designation?

Prior to marketing authorization, the FDA generally cannot publicly disclose whether a sponsor has submitted a Breakthrough Device designation request for a device, or whether FDA has granted or denied the request unless the sponsor decides to make that information available to the public. Additionally, the FDA plans to maintain a list of devices granted Breakthrough Device designation on its webpage, adding devices to the list once the device has received marketing authorization.

Breakthrough Devices Program Metrics

As of September 30, 2022, CDRH and CBER have granted 728 Breakthrough Device designations, including devices originally designated under the Expedited Access Pathway (EAP) program. The following graphs provide the distribution of these designations by fiscal year as well as by clinical panel.

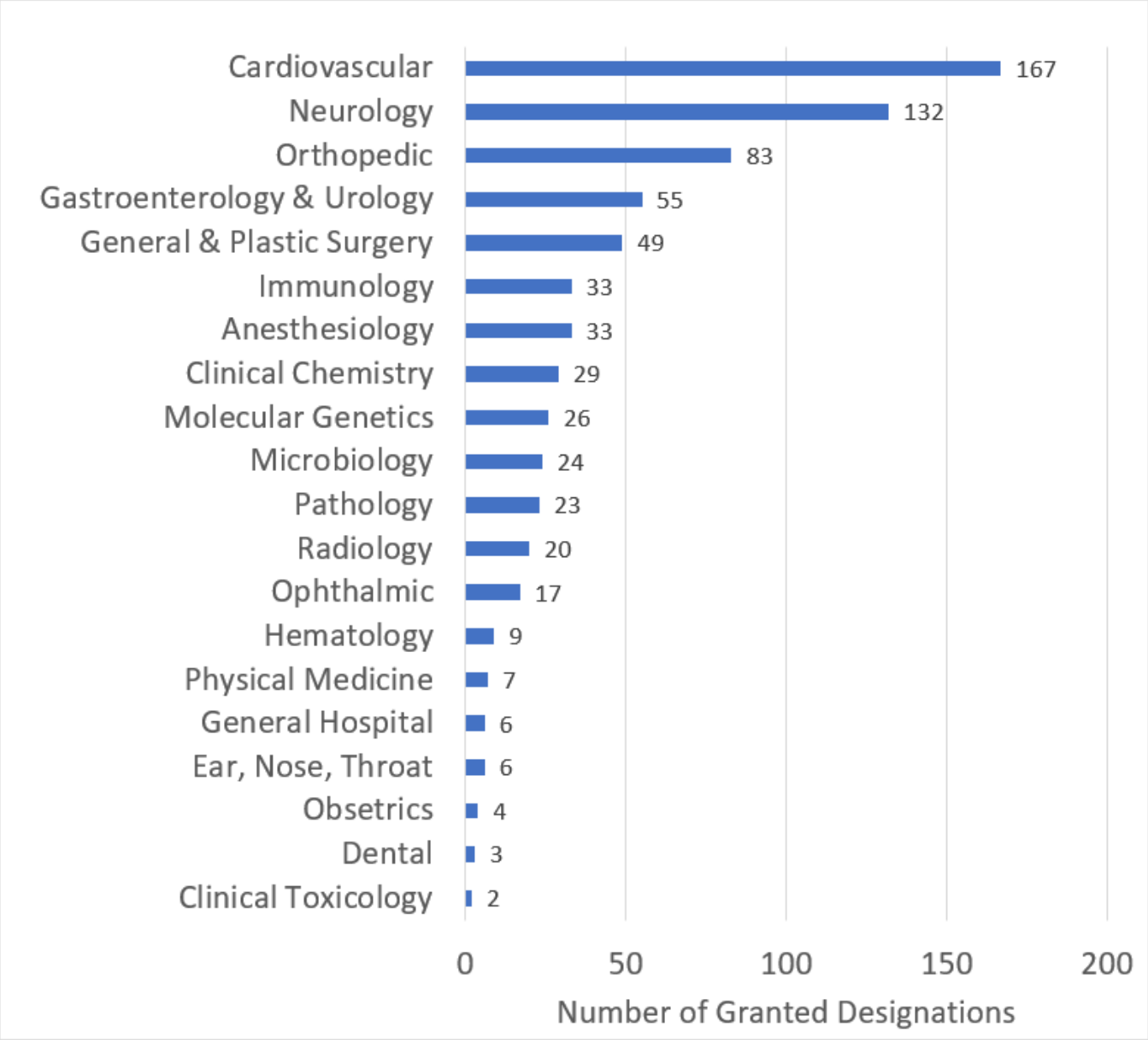
Graph 1: Number of Granted Breakthrough Device Designations by Fiscal Year [1]



Of the 728 devices granted Breakthrough Device designation, CDRH has granted 722 and CBER has granted 6.

*Data includes devices that were designated under the precursor Expedited Access Pathway (EAP). Since the vision and designation criteria between the precursor EAP Program and the Breakthrough Devices Program are consistent, the FDA considers devices granted designation under the EAP to be a part of the Breakthrough Devices Program.

Graph 2: Number of Granted Breakthrough Device Designations by Clinical Panel



CDRH and CBER Breakthrough Device Marketing Authorizations

Below is a list of CDRH and CBER Breakthrough Devices that have obtained marketing authorization.

CDRH and CBER Breakthrough Device Marketing Authorizations

Data as of September 30, 2022

Total of 56 Marketing Authorizations, including 54 CDRH devices and 2 CBER devices

Search:

Show entries

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
PHAGENESIS LIMITED	PHAGENYX SYSTEM	DEN220025 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN220025)	09/16/2022
MAGNUS MEDICAL, INC.	MAGNUS NEUROMODULATION SYSTEM (MNS) WITH SAINT TECHNOLOGY, MODEL NUMBER 1001K	K220177 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220177)	09/01/2022
RENOVIA, INC.	LEVA PELVIC HEALTH SYSTEM	K213913 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213913)	06/30/2022
EARLITEC DIAGNOSTICS, INC.	EARLIPOINT SYSTEM	K213882 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213882)	06/08/2022
SI-BONE, INC.	IFUSE BEDROCK GRANITE IMPLANT SYSTEM	K220195 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220195)	05/26/2022
NEUROMETRIX, INC.	QUELL-FM	DEN210046 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210046)	05/18/2022
BONESUPPORT AB	CERAMENT G	DEN210044 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210044)	05/17/2022
W. L. GORE & ASSOCIATES, INC.	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	P210032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210032)	05/13/2022
FUJIREBIO DIAGNOSTICS, INC.	LUMIPULSE G ß-AMYLOID RATIO (1-42/1-40)	DEN200072 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200072)	05/04/2022
TRANSMEDICS, INC.	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	P180051/S001 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180051S001)	04/27/2022
ULTRATHERA TECHNOLOGIES, INC.	GYROSTIM	K220231 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220231)	04/27/2022

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
VASCUTEK, LTD.	THORAFLEX HYBRID	P210006 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210006)	04/19/2022
CARTIHEAL, LTD.	AGILI-C	P210034 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210034)	03/29/2022
SPECTRANETICS, INC.	CAVACLEAR LASER SHEATH	DEN210024 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210024)	12/21/2021
KOIOS MEDICAL, INC.	KOIOS DS	K212616 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212616)	12/16/2021
APPLIEDVR, INC.	EASEVRX	DEN210014 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210014)	11/16/2021
SYNCTHINK, INC.	EYE-SYNC	K202927 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202927)	10/02/2021
PAIGE.AI	PAIGE PROSTATE	DEN200080 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200080)	09/21/2021
CANARY MEDICAL, INC.	CANARY TIBIAL EXTENSION WITH CANARY HEALTH IMPLANTED REPORTING PROCESSOR (CHIRP) SYSTEM	DEN200064 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200064)	08/27/2021
MICROTRANSPONDER, INC.	VIVISTIM PAIRED VNS SYSTEM	P210007 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210007)	08/27/2021
SIEMENS HEALTHCARE DIAGNOSTICS, INC.	ADVIA CENTAUR ENHANCED LIVER FIBROSIS (ELF)	DEN190056 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN190056)	08/20/2021
CARLSMED, INC.	APREVO TRANSFORAMINAL IBF	K210542 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210542)	06/30/2021
COGNOA, INC.	COGNOA ASD DIAGNOSIS AID	DEN200069 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200069)	06/02/2021

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
NEUROLUTIONS, INC.	NEUROLUTIONS IPSIHAND UPPER EXTREMITY REHABILITATION SYSTEM	DEN200046 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200046)	04/23/2021
HELIUS MEDICAL, INC.	PORTABLE NEUROMODULATION STIMULATOR (PONS)	DEN200050 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200050)	03/26/2021
MEDTRONIC, INC.	HARMONY TPV SYSTEM	P200046 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200046)	03/26/2021
SHOCKWAVE MEDICAL, INC.	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	P200039 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200039)	02/12/2021
ABBOTT LABORATORIES	I-STAT ALINITY SYSTEM	K201778 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201778)	01/08/2021
CARLSMED, INC.	APREVO INTERVERTEBRAL BODY FUSION DEVICE	K202034 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202034)	12/03/2020
CERUS CORPORATION	INTERCEPT BLOOD SYSTEM FOR PLASMA	BP130076/S034 (https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/intercept-blood-system-plasma)	11/24/2020
NIGHTWARE, INC.	NIGHTWARE KIT	DEN200033 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200033)	11/06/2020
FOUNDATION MEDICINE, INC.	FOUNDATIONONE LIQUID CDX	P200006 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200006)	10/26/2020
ROCHE MOLECULAR SYSTEMS, INC.	COBAS BKV	K202215 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202215)	09/02/2020

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
MEDTRONIC MINIMED, INC.	MINIMED 770G SYSTEM	P160017/S076 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017S076)	08/31/2020
FOUNDATION MEDICINE, INC.	FOUNDATIONONE LIQUID CDX	P190032 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190032)	08/26/2020
GUARDANT HEALTH, INC.	GUARDANT360 CDx	P200010 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200010)	08/07/2020
ROCHE MOLECULAR SYSTEMS, INC.	COBAS EBV	DEN200015 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200015)	07/30/2020
AMBU INNOVATION GMBH	AMBU DUODENO SYSTEM	K201098 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201098)	07/17/2020
BAY LABS, INC.	CAPTION GUIDANCE	DEN190040 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN190040)	02/07/2020
BOSTON SCIENTIFIC	EXALT MODEL D, SINGLE-USE DUODENOSCOPE, EXALT CONTROLLER	K193202 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193202)	12/13/2019
TUSKER MEDICAL	TULA SYSTEM	P190016 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190016)	11/25/2019
ORASURE TECHNOLOGIES	ORAQUICK EBOLA RAPID ANTIGEN TEST	DEN190025 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN190025)	10/10/2019
CVRX, INC.	BAROSTIM NEO SYSTEM	P180050 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050)	08/16/2019
IMPULSE DYNAMICS, INC.	OPTIMIZER SMART SYSTEM	P180036 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180036)	03/21/2019
PEAR THERAPEUTICS	RESET-O	K173681 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173681)	12/10/2018

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
SPIRATION, INC.	SPIRATION VALVE SYSTEM	P180007 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180007)	12/03/2018
AVITA MEDICAL, LLC.	RECELL AUTOLOGOUS CELL HARVESTING DEVICE	BP170122 (https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/recell-autologous-cell-harvesting-device)	09/20/2018
PULMONX CORPORATION	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	P180002 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180002)	06/29/2018
MEDTRONIC MINIMED, INC.	MINIMED 670G SYSTEM	P160017/S031 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017S031)	06/21/2018
CLINICAL RESEARCH CONSULTANTS, INC.	CUSTOMFLEX ARTIFICIAL IRIS	P170039 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170039)	05/30/2018
IDX, LLC	IDX-DR	DEN180001 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN180001)	04/11/2018
CONCENTRIC MEDICAL, INC.	TREVO PRO VUE RETRIEVER AND TREVO XP PRO VUE RETRIEVER (TREVO RETRIEVER)	K173352 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173352)	02/15/2018
BANYAN BIOMARKERS, INC.	BANYAN BTI	DEN170045 (https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170045.pdf)	02/14/2018
EMPATICA SRL	EMBRACE	K172935 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K172935)	01/26/2018
FOUNDATION MEDICINE, INC.	FOUNDATIONONE CDX	P170019 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170019)	11/30/2017
INSIGHTEC	EXABLATE	P150038 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038)	07/11/2016

Showing 1 to 56 of 56 entries

Previous 1 Next

Guidances related to Breakthrough Devices

- Draft Guidance: Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care (/regulatory-information/search-fda-guidance-documents/select-updates-breakthrough-devices-program-guidance-reducing-disparities-health-and-health-care)
- Breakthrough Devices Program Final Guidance (/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program)
- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de) (Benefit Risk Final Guidance)
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics - Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/benefit-risk-factors-consider-when-determining-substantial-equivalence-premarket-notifications-510k)
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program)

Contact Us

For any questions about the Breakthrough Devices program, please contact BreakthroughDevicesProgram@fda.hhs.gov (mailto:BreakthroughDevicesProgram@fda.hhs.gov).

---

1. Before August 3, 2022, this graph showed the number of granted Breakthrough Device designations by fiscal year in which the FDA received the request. This graph has been updated to show the number of granted Breakthrough Device designations by fiscal year in which the FDA granted its designation.