Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kristle Green, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3130, *CDERODSIRPublicMeetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 2020 (85 FR 68342), FDA published a notice with a 60-day comment period to announce and request comments on a virtual public meeting entitled ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security'' held on December 8 and 9, 2020. FDA is reopening the comment period until June 22, 2021.

The Agency believes that an additional 90 days will allow adequate time for interested persons to submit comments. Materials from the public meeting are on FDA's website at *https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security.*

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06053 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–M–3841, FDA–2018–M–3842, FDA–2018–M–3983, FDA–2018–M–4033, FDA–2018–M–4205, FDA–2018–M–4580, FDA–2018–M–4582, FDA–2018–M–4665, FDA–2018–M–4777, FDA–2018–M–4778, FDA–2018–M–4779, FDA–2018–M–4780, FDA–2018–M–4916, FDA–2019–M–0027, FDA–2019–M–0028, FDA–2019–M–0505, FDA–2019–M–0645, FDA–2019–M–0802, FDA–2019–M–0885, FDA–2019–M–0995, FDA–2019–M–1214, FDA–2019–M–1251, FDA–2019–M–1310, FDA–2019–M–1313, FDA–2019–M–1465, FDA–2019–M–1506, FDA–2019–M–1582, FDA–2019–M–1763, FDA–2019–M–1848, FDA–2019–M–1979, FDA–2019–M–1998, FDA–2019–M–2052, FDA–2019–M–2193, FDA–2019–M–2408, FDA–M–2522, FDA–2019–M–2560, FDA–2019–M–2561, FDA–2019–M–2671, FDA–2019–M–2732, FDA–2019–M–2753, FDA–2019–M–2782, FDA–2019–M–3309, FDA–2019–M–3513, FDA–2019–M–3652, FDA–2019–M–3845, FDA–2019–M–3863, FDA–2019–M–3844, FDA–2019–M–4007, FDA–2019–M–4153, FDA–2019–M–4186, FDA–2019–M–4238, FDA–2019–M–4928, FDA–2019–M–4978, FDA–2019–M–5393, FDA–2019–M–5438, FDA–2019–M–5534, FDA–2019–M–5605, FDA–2019–M–5683, FDA–2019–M–5741, FDA–2019–M–5857, FDA–2019–M–5961, FDA–2020–M–0097, FDA–2020–M–0107, FDA–2020–M–0108, FDA–2020–M–0495, FDA–2020–M–0985, FDA–2020–M–0984, FDA–2020–M–0986, FDA–2020–M–1083, FDA–2020–M–1115, FDA–2020–M–1116, FDA–2020–M–1175, FDA–2020–M–1213, FDA–2020–M–1214, FDA–2020–M–1267, FDA–2020–M–1286, FDA–2020–M–1290, FDA–2020–M–1299, FDA–2020–M–1300, FDA–2020–M–1311, FDA–2020–M–1358, FDA–2020–M–1367, FDA–2020–M–1410, FDA–2020–M–1420, FDA–2020–M–1527, FDA–2020–M–1583, FDA–2020–M–1600, FDA–2020–M–1612, FDA–2020–M–1613, FDA–2020–M–1715, FDA–2020–M–1724, FDA–2020–M–1726, FDA–2020–M–1748, FDA–2020–M–1752, FDA–2020–M–1760, FDA–2020–M–1821, FDA–2020–M–1783, FDA–2020–M–1822, FDA–2020–M–1828, FDA–2020–M–1830, FDA–2020–M–1829, FDA–2020–M–1835, FDA–2020–M–1838, FDA–2020–M–1868, FDA–2020–M–1986, FDA–2020–M–2021, FDA–2020–M–2288, FDA–2020–M–2248, and FDA–2020–M–2339]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved from October 1, 2018, through December 31, 2020. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2018–M–3841, FDA–2018–M–3842, FDA–2018–M–3983, FDA–2018–M–4033, FDA–2018–M–4205, FDA–2018–M–4580, FDA–2018–M–4582, FDA–

2018–M–4665, FDA–2018–M–4777, FDA–2018–M–4778, FDA–2018–M–4779, FDA–2018–M–4780, FDA–2018–M–4916, FDA–2019–M–0027, FDA–2019–M–0028, FDA–2019–M–0505, FDA–2019–M–0645, FDA–2019–M–0802, FDA–2019–M–0885, FDA–2019–M–0995, FDA–2019–M–1214, FDA–2019–M–1251, FDA–2019–M–1310, FDA–2019–M–1313, FDA–2019–M–1465, FDA–2019–M–1506, FDA–2019–M–1582, FDA–2019–M–1763, FDA–2019–M–1848, FDA–2019–M–1979, FDA–2019–M–1998, FDA–2019–M–2052, FDA–2019–M–2193, FDA–2019–M–2408, FDA–2019–M–2522, FDA–2019–M–2560, FDA–2019–M–2561, FDA–2019–M–2671, FDA–2019–M–2732, FDA–2019–M–2753, FDA–2019–M–2782, FDA–2019–M–3309, FDA–2019–M–3513, FDA–2019–M–3652, FDA–M–3845, FDA–2019–M–3862, FDA–2019–M–3863, FDA–2019–M–3844, FDA–2019–M–4007, FDA–2019–M–4153, FDA–2019–M–4186, FDA–2019–M–4238, FDA–2019–M–4928, FDA–2019–M–4978, FDA–2019–M–5393, FDA–2019–M–5438, FDA–2019–M–5534, FDA–2019–M–5605, FDA–2019–M–5683, FDA–2019–M–5741, FDA–2019–M–5857, FDA–2019–M–5961, FDA–2020–M–0097, FDA–2020–M–0107, FDA–2020–M–0108, FDA–2020–M–0495, FDA–2020–M–0985, FDA–2020–M–0984, FDA–2020–M–0986, FDA–2020–M–1083, FDA–2020–M–1115, FDA–2020–M–1116, FDA–2020–M–1175, FDA–2020–M–1213, FDA–2020–M–1214, FDA–2020–M–1267, FDA–2020–M–1286, FDA–2020–M–1290, FDA–2020–M–1299, FDA–2020–M–1300, FDA–2020–M–1311, FDA–2020–M–1358, FDA–2020–M–1367, FDA–2020–M–1410, FDA–2020–M–1420, FDA–2020–M–1527, FDA–2020–M–1583, FDA–2020–M–1600, FDA–2020–M–1612, FDA–2020–M–1613, FDA–2020–M–1715, FDA–2020–M–1724, FDA–2020–M–1726, FDA–2020–M–1748, FDA–2020–M–1752, FDA–2020–M–1760, FDA–2020–M–1821, FDA–2020–M–1783, FDA–2020–M–1822, FDA–2020–M–1828, FDA–2020–M–1830, FDA–2020–M–1829, FDA–2020–M–1835, FDA–2020–M–1838, FDA–2020–M–1868, FDA–2020–M–1986, FDA–2020–M–2021, FDA–2020–M–2288, FDA–2020–M–2248, and FDA–2020–M–2339 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Dharmesh Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–3289.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is published in the **Federal Register**. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a list of available safety and effectiveness summaries of PMA approvals and denials that were announced. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the internet from October 1, 2018, through December 31, 2020. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS AND SAFETY AND PROBABLE BENEFIT SUMMARIES FOR APPROVED HDES MADE AVAILABLE FROM OCTOBER 1, 2018, THROUGH DECEMBER 31, 2020

PMA No., Docket No.	Applicant	Trade name	Approval date
P180003, FDA–2018–M–3841	Veryan Medical Ltd	BioMimics 3D Vascular Stent System	10/4/2018
P150040/S003, FDA–2018–M–3842.	Carl Zeiss Meditec, Inc	VisuMax Femtosecond Laser	10/4/2018
P160054/S008, FDA–2018–M–3983.	Thoratec Corp	HeartMate 3 Left Ventricular Assist System	10/18/2018
P100040/S036, FDA–2018–M–4033.	Medtronic Vascular	Valiant Navion™ Thoracic Stent Graft System	10/19/2018
P180010, FDA–2018–M–4205	W.L. Gore & Associates, Inc	GORE Carotid Stent	11/1/2018
P150002, FDA–2018–M–4580	Cordis Corp	Cordis INCRAFT® AAA Stent Graft System	11/27/2018

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PMA No., Docket No.	Applicant	Trade name	Approval date
P120016/S024, FDA–2018–M–4582.	Cardiva Medical, Inc	VASCADE® MVP Venous Vascular Closure System	11/27/2018
P180007, FDA–2018–M–4665	Spiration, Inc	Spiration® Valve System	12/3/2018
P160034, FDA–2018–M–4672	Cardiac Science Corp	Powerheart® G3 Pro AED	12/6/2018
P160033, FDA–2018–M–4675	Cardiac Science Corp	Powerheart® G5 AED, Powerheart® AED G3 Plus, And Powerheart® AED G3.	12/7/2018
P160043/S012, FDA–2018–M–4777.	Medtronic Vascular	Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System.	12/14/2018
P110013/S088, FDA–2018–M–4778.	Medtronic Vascular	Resolute Integrity Zotarolimus-Eluting Coronary Stent System.	12/14/2018
P100018/S015, FDA–2018–M–4779.	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular.	Pipeline™ Flex Embolization Device	12/14/2018
P150038/S006, FDA–2018–M–4780.	InSightec, Inc	Exablate Model 4000 Types 1.0 and 1.1 System (Exablate Neuro).	12/16/2018
P170018, FDA–2018–M–4916	Physio-Control, Inc	LIFEPAK® CR2 Defibrillator	12/21/2018
P170032, FDA–2019–M–0027	Sequent Medical, Inc	Woven EndoBridge (WEB) Aneurysm Embolization System	12/31/2018
P180001, FDA–2019–M–0028	William Cook Europe ApS	Zenith® Dissection Endovascular System	12/31/2018
P170037, FDA–2019–M–0505	OPKO Diagnostics, LLC	Sangia Total PSA Test	1/30/2019
P180025, FDA–19M–2526	Essential Medical, Inc	MANTA™ Vascular Closure Device	2/1/2019
P170036, FDA–2019–M–0645	Spinal Kinetics LLC	M6–C™ Artificial Cervical Disc	2/6/2019
P160050, FDA–2019–M–0802	Intrinsic Therapeutics	Barricaid® Anular Closure Device (ACD)	2/8/2019
P170030, FDA–2019–M–0885	Biotronik, Inc	Orsiro Sirolimus Eluting Coronary Stent System (Orsiro Stent System).	2/22/2019
P170042/S002, FDA–2019–M–0995.	C.R. Bard, Inc	COVERA™ Vascular Covered Stent	3/1/2019
P160002/S009, FDA–2019–M–1310.	Ventana Medical System, Inc	VENTANA PD–L1 (SP142) Assay	3/8/2019
P180037, FDA–2019–M–1214	Bard Peripheral Vascular, Inc. (BPV).	VENOVO Venous Stent System	3/13/2019
P100009/S028, FDA–2019–M–1251.	Abbott Vascular, Inc	MitraClip NT Clip Delivery System; MitraClip NTR/XTR Clip Delivery System.	3/14/2019
P180036, FDA–2019–M–1313	Impulse Dynamics (USA), Inc	OPTIMIZER Smart System	3/21/2019
P180040, FDA–2019–M–1465	Fidia Pharma USA, Inc	TRILURON™	3/26/2019
P180032, FDA–2019–M–1506	Channel Medsystems, Inc	Cerene® Cryotherapy Device	3/28/2019
P170027, FDA–2019–M–1582	TherOx, Inc	TherOx DownStream System	4/2/2019
P180034, FDA–2019–M–1763	Intact Vascular, Inc	Tack Endovascular System® (6F)	4/11/2019
P180043, FDA–2019–M–1979	QIAGEN Manchester Ltd	*therascreen*® FGFR RGQ RT–PCR Kit	4/12/2019
P180024, FDA–2019–M–1848	BAROnova, Inc	TransPyloric Shuttle/TransPyloric Shuttle Delivery Device	4/16/2019
P180029, FDA–2019–M–1998	Boston Scientific Corp	LOTUS Edge™ Valve System	4/23/2019
P180014, FDA–2019–M–2052	XVIVO Perfusion, Inc	XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate.	4/26/2019
P180013, FDA–2019–M–2193	Boston Scientific Corp	VICI VENOUS STENT® System	5/2/2019
P180031, FDA–2019–M–2408	Stryker Neurovascular	Neuroform Atlas® Stent System	5/16/2019
H180002, FDA–2019–M–2522	Novocure, Ltd	NovoTTF™-100L System	5/23/2019
P190001, FDA–2019–M–2560	QIAGEN GmbH	*therascreen* PIK3CA RGQ PCR Kit	5/24/2019
P190004, FDA–2019–M–2561	QIAGEN GmbH	*therascreen* PIK3CA RGQ PCR Kit	5/24/2019
P160013/S002, FDA–2019–M–2671.	TransMedics, Inc	Organ Care System (OCS™) Lung System	5/31/2019
P160036, FDA–2019–M–2732	DT MedTech, LLC	Hintermann Series H3™ Total Ankle Replacement System	6/4/2019
P160048/S006, FDA–2019–M–2753.	Senseonics, Inc	Eversense Continuous Glucose Monitoring System	6/6/2019
P160029, FDA–2019–M–2782	Philips Medical Systems, Inc	HeartStart OnSite Defibrillator (Model M5066A), HeartStart Home Defibrillator (Model M5068A), Primary Battery (Model M5070A), SMART Pads Cartridges (Adult Model M5071A) and Infant/Child (Model M5072A).	6/6/2019
P150013/S014, FDA–2019–M–3309.	Dako North America, Inc	PD–L1 IHC 22C3 pharmDx	6/10/2019
P000025/S104, FDA–2019–M–3513.	MED–EL Corp	MED–EL Cochlear Implant System	7/19/2019
P150013/S016, FDA–2019–M–3652.	Dako North America, Inc	PD–L1 1HC 22C3 pharmDx	7/30/2019
P140031/S085, FDA–2019–M–3845.	Edwards Lifesciences LLC	Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System.	8/16/2019
H190005, FDA–2019–M–3863	Zimmer Biomet Spine, Inc	The Tether™—Vertebral Body Tethering System	8/16/2019
P180050, FDA–2019–M–3862	CVRx, Inc	BAROSTIM NEO® System	8/16/2019
P130021/S058, FDA–2019–M–3844.	Medtronic CoreValve LLC	Medtronic CoreValve Evolut R System and Medtronic CoreValve Evolut PRO System.	8/16/2019
H170001, FDA–2019–M–4007	ApiFix, Ltd	Minimally Invasive Deformity Correction (MID–C) System	8/23/19

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PMA No., Docket No.	Applicant	Trade name	Approval date
P040020/S087, FDA–2019–M–4153.	Alcon Laboratories, Inc	AcrySof® IQ PanOptix® Trifocal Intraocular Lens (Model TFNT00) and AcrySof® IQ PanOptix® Toric Trifocal Intraocular Lens (Models TFNT30, TFNT40, TFNT50 and TFNT60).	8/26/2019
P190006, FDA–2019–M–4186	Axonics Modulation Technologies, Inc.	Axonics Sacral Neuromodulation System	9/6/2019
P930016/S057, FDA–2019–M–4238.	AMO Manufacturing USA, LLC.	iDESIGN® Refractive Studio and STAR S4 IR® Excimer Laser Systems.	9/9/2019
P190011, FDA–2019–M–4928	DiaSorin Inc	LIAISON XL MUREX HCV Ab LIAISON XL MUREX Control HCV Ab.	10/18/2019
P190014, FDA–2019–M–4978	Myriad Genetic Laboratories, Inc.	Myriad myChoice® CDx	10/23/2019
P180046, FDA–2019–M–5393	Axonics Modulation Technologies, Inc.	Axonics Sacral Neuromodulation System	11/13/2019
P180035, FDA–2019–M–5438	CooperVision, Inc	MiSight 1 Day (omafilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear.	11/15/2019
P190008, FDA–2019–M–5534	Medtronic, Inc	IN.PACT™ AV Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter.	11/21/2019
P190016, FDA–2019–M–5605	Tusker Medical, Inc	Tula® System	11/25/2019
P180047, FDA–2019–M–5683	DiaSorin, Inc	LIAISON QuantiFERON—TB Gold Plus, LIAISON Control QuantiFERON—TB Gold Plus and LIAISON QuantiFERON Software.	11/26/2019
P170019/S006, FDA–2019–M–5741.	Foundation Medicine, Inc	FoundationOne® CDx	12/3/2019
P170038, FDA–2019–M–5857	Abbott	CentriMag Circulatory Support System	12/6/2019
P180027, FDA–2019–M–5961	MicroVention, Inc	Flow Re-Direction Endoluminal Device (FRED®) System	12/16/2019
P140009/S039, FDA–2020–M–0097.	Abbott Medical, Inc	Abbott Infinity™ DBS System	1/2/2020
P180038, FDA–2020–M–0107	DiaSorin, Inc	LIAISON® XL MUREX Anti-HBc, LIAISON® XL MUREX Control Anti-HBc.	1/2/2020
P190018, FDA–2020–M–0108	Alcon Research, Inc	Clareon™ Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) (Model Number: SY60WF); Clareon™ Toric Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) (Model Numbers: CNW0T3, CNW0T4, CNW0T5, CNW0T6, CNW0T7, CNW0T8 and CNW0T9); Clareon™ Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) with the AutonoMe™ Pre-loaded Delivery System (Model Number: CNA0T0); Clareon™ Toric Aspheric Hydrophobic Acrylic Intraocular Lens (IOL) with the AutonoMe™ Pre-loaded Delivery System (Model Numbers: CNA0T3, CNA0T4, CNA0T5, CNA0T6, CNA0T7, CNA0T8 and CNA0T9).	1/7/2020
P170023, FDA–2020–M–0495	Contura International A/S	Bulkamid® Urethral Bulking System	1/28/2020
P170022, FDA–2020–M–0985	ARJ Medical, Inc	PyloPlus UBT System	2/18/2020
P180039, FDA–2020–M–0984	DiaSorin Inc	LIAISON® XL MUREX Anti-HBs; LIAISON® XL MUREX Control Anti-HBs; LIAISON® XL MUREX Anti-HBs Verifiers.	2/21/2020
P930014/S126, FDA–2020–M–0986.	Alcon Laboratories, Inc	AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (Model DFT015); AcrySof™ IQ Vivity™ Toric Extended Vision IOLs (DFT315, DFT 415, DFT515); AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL (DAT015); AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOLs (DAT315, DAT415, DAT515).	2/26/2020
P190024, FDA–2020–M–1083	Ventana Medical Systems, Inc	CINtec® *PLUS* Cytology	3/10/2020
P120006/S031, FDA–2020–M–1126.	Endologix, Inc	Alto™ Abdominal Stent Graft System	3/13/2020
P980033/S050, FDA–2020–M–1115.	Boston Scientific Corp	VENOUS WALLSTENT	3/17/2020
P970051/S172, FDA–2020–M–1116.	Cochlear Americas	Nucleus 24 Cochlear Implant System	3/17/2020
P190025, FDA–2020–M–1175	Abbott Molecular, Inc	Alinity m HCV	3/23/2020
P140029/S021, FDA–2020–M–1214.	Q-Med AB, a Galderma affiliate.	Restylane® Kysse	3/26/2020
P190028, FDA–2020–M–1213	Roche Molecular Systems, Inc	cobas HPV for use on the cobas 6800/8800 Systems	4/3/2020
P190027, FDA–2020–M–1286	Intact Vascular, Inc	Tack Endovascular System® (4F, 1.5–4.5mm)	4/10/2020
P050010/S020, FDA–2020–M–1267.	Centinel Spine, LLC	prodisc® L Total Disc Replacement	4/10/2020
P130008/S039, FDA–2020–M–1299.	Inspire Medical Systems, Inc	Inspire® Upper Airway Stimulation (UAS)	4/14/2020

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS AND SAFETY AND PROBABLE BENEFIT SUMMARIES FOR APPROVED HDES MADE AVAILABLE FROM OCTOBER 1, 2018, THROUGH DECEMBER 31, 2020—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P190026, FDA–2020–M–1290	QIAGEN GmbH	therascreen® BRAF V600E RGQ PCR Kit	4/15/2020
P170019/S013, FDA–2020–M–1300.	Foundation Medicine, Inc	FoundationOne® CDx (F1CDx)	4/17/2020
P190015, FDA–2020–M–1311	Bolton Medical Inc	TREO® Abdominal Stent-Graft System	5/4/2020
P170019/S011, FDA–2020–M–1358.	Foundation Medicine, Inc	FoundationOne® CDx (F1CDx)	5/6/2020
P160028, FDA–2020–M–1367	Philips Medical Systems, Inc	HeartStart FR3 Defibrillators Models 861388 (Text) and 861389 (ECG Display), Primary Battery (Models 989803150161, 989803150171), Rechargeable Battery (Model 989803150241), Charger for the Rechargeable Battery (Model 861394), SmartPads III (Models 989803149981, 989803149991), DP pads (Models 989803158211, 989803158221), and Pediatric Key (Model 989803150031).	5/11/2020
P180028, FDA–2020–M–1368	Philips Medical Systems, Inc	HeartStart FRx Defibrillator (861304), Primary Battery (M5070A), Aviation FRx Battery (989803139301), SMART Pads II (989803139261), and Infant/Child Key (989803139311).	5/11/2020
P150025/S013, FDA–2020–M–1410.	Dako North America, Inc	PD–L1 IHC 28–8 pharmDx	5/15/2020
P170019/S015, FDA–2020–M–1420.	Foundation Medicine, Inc	FoundationOne® CDx	5/19/2020
P110033/S047, FDA–2020–M–1527.	Allergan	JUVÉDERM® VOLUMA™ XC	6/12/2020
P190021, FDA–2020–M–1583	Mainstay Medical Ltd	ReActiv8 Implantable Neurostimulation System	6/16/2020
P170019/S016, FDA–2020–M–1612.	Foundation Medicine, Inc	FoundationOne® CDx (F1CDx)	6/16/2020
P200014, FDA–2020–M–1600	Roche Molecular Systems, Inc	cobas® EZH2 Mutation Test	6/18/2020
P100010/S098, FDA–2020–M–1613.	Medtronic, Inc	Arctic Front Advance™ Cardiac Cryoablation Catheter Arctic Front Advance Pro™ Cardiac Cryoablation Catheters Freezor™ *MAX* Cardiac Cryoablation Catheter CryoConsole Manual Retraction Kit.	6/23/2020
P130013/S035, FDA–2020–M–1715.	Boston Scientific Corp	WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Left Atrial Appendage Closure Device with Delivery System.	7/21/2020
P190031, FDA–2020–M–1724	Ventana Medical Systems, Inc	VENTANA HER2 Dual ISH DNA Probe Cocktail	7/28/2020
P180031/S001, FDA–2020–M–1726.	Stryker Neurovascular	Neuroform Atlas® Stent System	7/30/2020
P200010, FDA–2020–M–1748	Guardant Health, Inc	Guardant360® CDx	8/7/2020
P190007, FDA–2020–M–1752	Cardinal Health	Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK–COMBO Pacing/Defibrillation/ECG Electrodes.	8/7/2020
P150003/S058, FDA–2020–M–1760.	Boston Scientific Corp	SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™); SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-The-Wire™); SYNERGY™ XD Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™).	8/10/2020
P190032, FDA–2020–M–1821	Foundation Medicine, Inc	FoundationOne Liquid CDx	8/26/2020
P180048, FDA–2020–M–1783	Diasorin, Inc	LIAISON® XL MUREX HBeAg, LIAISON® XL MUREX Control HBeAg.	8/29/2020
P180049, FDA–2020–M–1822	Diasorin, Inc	LIAISON® XL MUREX anti-HBe, LIAISON® XL MUREX Control Anti-HBe.	8/29/2020
P180045, FDA–2020–M–1828	Diasorin, Inc	LIAISON® XL MUREX HBc IgM, LIAISON® XL MUREX Control HBc IgM.	8/29/2020
P200013, FDA–2020–M–1830	Abbott Molecular, Inc	Alinity m HBV	8/29/2020
P190017, FDA–2020–M–1829	Diasorin, Inc	LIAISON® XL MUREX HBsAg Qual; LIAISON® MUREX Control HBsAg Qual; LIAISON® XL MUREX HBsAg Confirmatory Test.	8/29/2020
P200015, FDA–2020–M–1835	Edwards Lifesciences, LLC	Edwards SAPIEN 3 Transcatheter Heart Valve System with Edwards Commander Delivery System.	8/31/2020
P160017/S076, FDA–2020–M–1838.	Medtronic Minimed, Inc	MiniMed 770G System	8/31/2020
P140031/S112, FDA–2020–M–1868.	Edwards Lifesciences, LLC	Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System.	9/9/2020
P200022, FDA–2020–M–1986	Simplify Medical, Inc	Simplify® Cervical Artificial Disc	9/18/2020
P160042/S010, FDA–2020–M–2021.	Prollenium Medical Technologies, Inc.	Revanesse® Lips+	9/21/2020

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PMA No., Docket No.	Applicant	Trade name	Approval date
H190001, FDA–2020–M–2248	HDL Therapeutics, Inc	Plasma Delipidation System (PDS–2™ System)	12/1/2020
P190030, FDA–2020–M–2288	Theragen, Inc	ActaStim-S Spine Fusion Stimulator	12/9/20
P200030, FDA–2020–M–2339	W. L. Gore and Associates, Inc.	GORE® EXCLUDER® Conformable AAA Endoprosthesis (EXCC).	12/22/20

II. Electronic Access

Persons with access to the internet may obtain the documents at *https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: March 15, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06052 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

The meeting will be held as a virtual meeting and open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast *https://videocast.nih.gov/* and the CCRHB website *https://ccrhb.od.nih.gov/meetings.html.*

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: April 23, 2021.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: Clinical Center CEO Update, Patient Safety and Clinical Quality Update, other business of the Board.

Place: National Institutes of Health, Building 1, 9000 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: March 18, 2021.

Patricia B. Hansberger,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–06021 Filed 3–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, May 12, 2021, 10:00 a.m. to May 13, 2021, 01:45 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on December 28, 2020, 85 FR 84358.

This notice is being amended to change the meeting time from 10:00 a.m.–1:15 p.m. on May 12, 2021 to 10:00 a.m.–3:00 p.m. on May 12, 2021. The meeting is to the public.

Dated: March 18, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–06020 Filed 3–23–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Docket ID: FEMA–2020–0036; OMB No. 1660–0105]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; National Household Survey on Disaster Preparedness

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the charge to FEMA and the Department of Homeland Security (DHS) to meet FEMA strategic priorities, and FEMA's program management to improve the public's knowledge and actions for preparedness and resilience. Information from this collection will be used to track changes in knowledge, attitudes, and behaviors related to preparedness in the general public. The Individual and Community Preparedness Division analyzes and uses data collected in FEMA Form 008–0–15, National Disaster Preparedness Survey to identify progress and gaps in individual and community preparedness to better understand the motivators and barriers to preparedness in general and about specific hazards. The survey measures the public's knowledge, attitudes, and behaviors relative to preparing for a wide range of hazards.

DATES: Comments must be submitted on or before April 23, 2021.

ADDRESSES: Written comments and recommendations for the proposed