FY 2020

Real Time Report

pursuant to the

Medical Device User Fee Amendments

as amended by the FDA Reauthorization Act of 2017

Acronyms

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

FY – Fiscal Year (October 1 to September 30)

MDUFA – Medical Device User Fee Amendments

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 738A(a)(1)(A)(iii) of the FD&C Act, as amended by section 903 of FDARA, requires the Food and Drug Administration (FDA) to provide "Real Time" reporting, posted on a quarterly basis, of guidance documents and public meetings related to the process for the review of devices.

Real Time Reporting Under Section 738A(a)(1)(A)(iii) of the FD&C Act

This report is being issued pursuant to the requirement of Section 738A(a)(1)(A)(iii) of the FD&C Act, which states:

> "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post…on the internet website of the Food and Drug Administration…
>
> - "The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017; and
> - "The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017."

Medical Devices

Guidance Documents

Pursuant to the MDUFA IV Commitment Letter,[1] the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA IV Commitment Letter are indicated as such.[2] The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).[3]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2020

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/intravascular-catheters-wires-and-delivery-systems-lubricious-coatings-labeling-considerations	10/10/2019	Yes	No	N/A	No
2	Q1	Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling www.fda.gov/regulatory-information/search-fda-guidance-documents/coronary-peripheral-and-neurovascular-guidewires-performance-tests-and-recommended-labeling	10/10/2019	Yes	No	N/A	No
3	Q1	Breast Implants - Certain Labeling Recommendations to Improve Patient Communication www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication	10/24/2019	Yes	No	N/A	A-List

[1] www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf; see section VI (Performance Reports)
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2020-fy-2020

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
4	Q1	Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices	11/14/2019	No	Yes	Sec. 704 of the FDA Reauthorization Act of 2017	A-List
5	Q1	Certificates of Confidentiality www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	11/25/2019	No	No	N/A	No
6	Q1	Magnetic Resonance (MR) Coil - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/magnetic-resonance-mr-coil-performance-criteria-safety-and-performance-based-pathway	12/9/2019	Yes	No	N/A	A-List
7	Q1	[4]Real-Time Premarket Approval Application (PMA) Supplements www.fda.gov/regulatory-information/search-fda-guidance-documents/real-time-premarket-approval-application-pma-supplements	12/16/2019	Yes	No	N/A	No
8	Q1	[4]FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic	12/16/2019	Yes	No	N/A	No
9	Q1	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/16/2019	Yes	No	N/A	No
10	Q1	[4]Annual Reports for Approved Premarket Approval Applications (PMA) www.fda.gov/regulatory-information/search-fda-guidance-documents/annual-reports-approved-premarket-approval-applications-pma	12/16/2019	Yes	No	N/A	No
11	Q1	[4]Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas	12/16/2019	Yes	No	N/A	No

[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q1	[4]30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes www.fda.gov/regulatory-information/search-fda-guidance-documents/30-day-notices-135-day-premarket-approval-pma-supplements-and-75-day-humanitarian-device-exemption	12/16/2019	Yes	No	N/A	No
13	Q1	Bridging for Drug-Device and Biologic-Device Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/bridging-drug-device-and-biologic-device-combination-products	12/19/2019	No	No	N/A	No
14	Q1	[4]Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket	12/20/2019	Yes	No	N/A	No
15	Q1	Requesting FDA Feedback on Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products	12/26/2019	Yes	Yes	Sec. 3038 of the 21st Century Cures Act	No
16	Q2	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-percutaneous-transluminal-angioplasty-pta-and-specialty-catheters-premarket-notification	1/13/2020	Yes	No	N/A	No
17	Q2	[4]Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-performance-assessment-considerations-computer-assisted-detection-devices-applied-radiology	1/22/2020	Yes	No	N/A	No

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18	Q2	Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions	1/28/2020	Yes	No	N/A	No
19	Q2	Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions	2/13/2020	Yes	No	N/A	No
20	Q2	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-dual-510k-and-clia-waiver-application-studies	2/26/2020	Yes	No	N/A	A-List
21	Q2	Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications	2/26/2020	No	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
22	Q2	Product Labeling for Laparoscopic Power Morcellators www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators	2/26/2020	Yes	No	N/A	No
23	Q2	[5]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	2/29/2020	No	No	N/A	No
24	Q2	Bone Anchors - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/bone-anchors-premarket-notification-510k-submissions	3/3/2020	Yes	No	N/A	No

[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.115(g)(2).

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25	Q2	Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/soft-hydrophilic-daily-wear-contact-lenses-performance-criteria-safety-and-performance-based-pathway	3/4/2020	Yes	No	N/A	A-List
26	Q2	[4]Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-510k-submissions-electrosurgical-devices-general-surgery	3/9/2020	Yes	No	N/A	No
27	Q2	510(k) Third Party Review Program www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program	3/12/2020	Yes	Yes	Sec. 206 of the FDA Reauthorization Act of 2017	A-List
28	Q2	[5]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	3/16/2020	No	No	N/A	No
29	Q2	Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/restricted-delivery-systems-flow-restrictors-oral-liquid-drug-products-guidance-industry	3/17/2020	No	No	N/A	No
30	Q2	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/18/2020	Yes	No	N/A	No
31	Q2	[5]Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic	3/19/2020	No	No	N/A	No

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32	Q2	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	3/20/2020	Yes	No	N/A	No
33	Q2	[5]Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus	3/22/2020	Yes	No	N/A	No
34	Q2	[5]Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health	3/25/2020	Yes	No	N/A	No
35	Q2	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/27/2020	Yes	No	N/A	No
36	Q2	[4]Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a	3/27/2020	No	No	N/A	No
37	Q2	[5]Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease	3/29/2020	Yes	No	N/A	No

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38	Q2	[5]Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health	3/30/2020	Yes	No	N/A	No
39	Q3	[5]Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health	4/2/2020	Yes	No	N/A	No
40	Q3	[5]Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public	4/4/2020	Yes	No	N/A	No
41	Q3	[5]Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public	4/5/2020	Yes	No	N/A	No
42	Q3	[5]Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease	4/6/2020	Yes	No	N/A	No
43	Q3	[5]Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during	4/6/2020	Yes	No	N/A	No

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44	Q3	Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-labeling-vitro-companion-diagnostic-devices-specific-group-oncology-therapeutic	4/14/2020	Yes	No	N/A	No
45	Q3	[5]Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease	4/14/2020	Yes	No	N/A	No
46	Q3	[5]Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health	4/16/2020	Yes	No	N/A	No
47	Q3	Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda	4/22/2020	Yes	No	N/A	No
48	Q3	Nonbinding Feedback After Certain FDA Inspections of Device Establishments www.fda.gov/regulatory-information/search-fda-guidance-documents/nonbinding-feedback-after-certain-fda-inspections-device-establishments	4/22/2020	No	Yes	Sec. 702 of the FDA Reauthorization Act of 2017	A-List
49	Q3	[5]Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient	4/23/2020	Yes	No	N/A	No

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50	Q3	[5]Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency	4/23/2020	Yes	No	N/A	No
51	Q3	[5]Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public	4/24/2020	Yes	No	N/A	No
52	Q3	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health	4/27/2020	Yes	No	N/A	No
53	Q3	Classification of Posterior Cervical Screw Systems: Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-posterior-cervical-screw-systems-small-entity-compliance-guide	5/4/2020	Yes	Yes	Sec. 212 of the Small Business Regulatory Enforcement Fairness Act	No
54	Q3	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	5/4/2020	No	No	N/A	No
55	Q3	[5]Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	5/6/2020	No	No	N/A	No

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56	Q3	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	5/11/2020	No	No	N/A	No
57	Q3	[5]Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic	5/11/2020	No	No	N/A	No
58	Q3	[5]Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/supplements-approved-premarket-approval-pma-or-humanitarian-device-exemption-hde-submissions-during	5/21/2020	Yes	No	N/A	No
59	Q3	[5]Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks	5/26/2020	No	No	N/A	No
60	Q3	[5]Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health	5/26/2020	Yes	No	N/A	No
61	Q3	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	6/5/2020	Yes	No	N/A	No

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62	Q3	[5]Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-considerations-clinical-trials-during-covid-19-public-health-emergency-guidance-industry	6/16/2020	Yes	No	N/A	No
63	Q3	[5]Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	6/19/2020	No	No	N/A	No
64	Q3	[5]Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices	6/22/2020	Yes	No	N/A	No
65	Q3	Review and Update of Device Establishment Inspection Processes and Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/review-and-update-device-establishment-inspection-processes-and-standards	6/29/2020	No	Yes	Sec. 702 of the FDA Reauthorization Act of 2017	N/A
66	Q4	[5]Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and	7/1/2020	No	No	N/A	No
67	Q4	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	7/2/2020	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
68	Q4	Select Updates for Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions	7/13/2020	Yes	No	N/A	No
69	Q4	Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign	7/14/2020	Yes	No	N/A	No
70	Q4	Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab	7/15/2020	Yes	Yes	Sec. 207 of the FDA Reauthorization Act of 2017	N/A
71	Q4	Clinical Investigations for Prostate Tissue Ablation Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigations-prostate-tissue-ablation-devices	7/15/2020	Yes	No	N/A	No
72	Q4	[5]Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health	7/20/2020	Yes	No	N/A	No
73	Q4	Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal	7/21/2020	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
74	Q4	Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	7/21/2020	No	No	N/A	No
75	Q4	Multiple Function Device Products: Policy and Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations	7/29/2020	Yes	No	N/A	A-List
76	Q4	Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/cutaneous-electrodes-recording-purposes-performance-criteria-safety-and-performance-based-pathway	8/14/2020	Yes	No	N/A	A-List
77	Q4	Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/conventional-foley-catheters-performance-criteria-safety-and-performance-based-pathway	8/14/2020	Yes	No	N/A	A-List
78	Q4	Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank www.fda.gov/regulatory-information/search-fda-guidance-documents/civil-money-penalties-relating-clinicaltrialsgov-data-bank	8/17/2020	No	No	N/A	No
79	Q4	Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use	8/31/2020	Yes	Yes	MDUFA Commitment Letter IV.F.3.a	A-List
80	Q4	[4]Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and	9/4/2020	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
81	Q4	Recognition and Withdrawal of Voluntary Consensus Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards	9/15/2020	Yes	No	N/A	A-List
82	Q4	[5]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	9/21/2020	Yes	No	N/A	No
83	Q4	The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
84	Q4	Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
85	Q4	Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and	9/25/2020	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017; MDUFA Commitment Letter IV.D.	A-List
86	Q4	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use	9/29/2020	Yes	No	N/A	B-List
87	Q4	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use	9/29/2020	Yes	No	N/A	B-List

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88	Q4	Breast Implants - Certain Labeling Recommendations to Improve Patient Communication www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication	9/29/2020	Yes	No	N/A	No
89	Q4	[4]Saline, Silicone Gel, and Alternative Breast Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants	9/29/2020	Yes	No	N/A	No

Public Meetings

Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, public meetings that are related to the process for the review of devices are listed in the table below.

Table 2: Public Meetings Held on Topics Related to the Process for the Review of Devices for FY 2020

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q2	Artificial Intelligence for Radiological Imaging Public Workshop	2/25-26/2020	No
2	Q2	Medical Extended-Reality Public Workshop - Towards Best Evaluation Practices in Virtual and Augmented Reality in Medicine	3/5/2020	No
3	Q2	DNA for Cancer Screening	3/9/2020	No
4	Q4	Spinal Device Premarket Application Review – Public Workshop	8/13/2020	No
5	Q4	Integrating Patient Preference Information in Medical Device Evaluation (Co-Sponsorship)	9/29/2020	No
6	Q4	Developing, Modifying, and Integrating Patient-Reported Outcome (PRO) Instruments into Medical Device Investigations	9/30/2020	No