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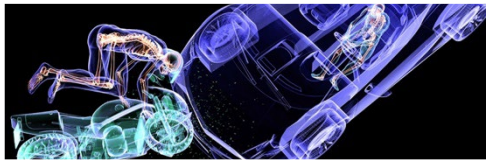
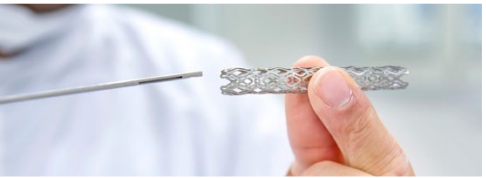

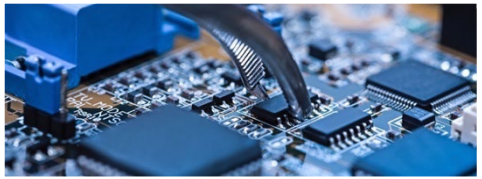



# Transition Out of COVID-19 Emergency:

## Demystifying the FDA Requirements to Keep Your Device on The Market

Christie Bergerson, Ph.D.
Jianlin Song, Esq.

April 25, 2023

# Disclaimer

Any recommendations are made for your consideration given our understanding of the most current information.

Examples provided in this presentation are for discussion purposes only and are not applicable to specific circumstances without additional consideration.

# Presenters


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# FDA Regulation of COVID-19

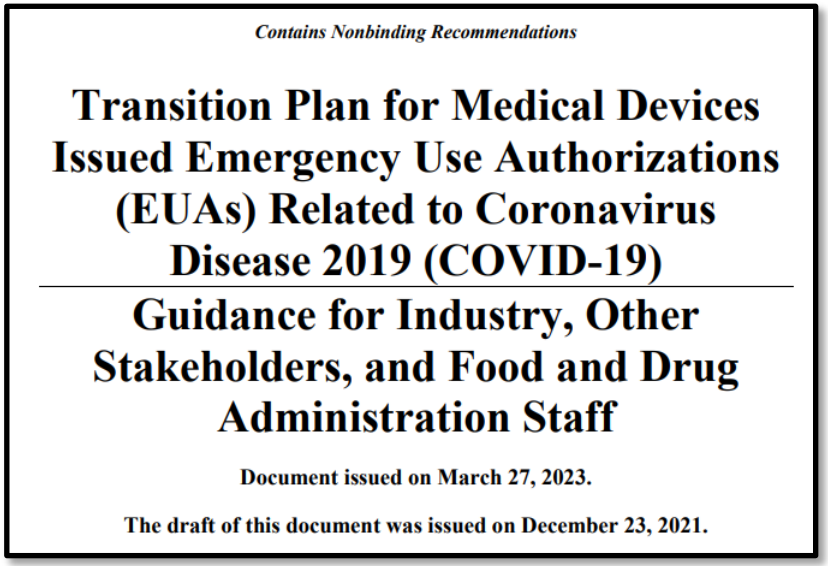
# FDA Medical Device Regulation

- All medical devices on market must go through FDA and be cleared/approved/authorized
  - Including COVID-19 diagnostic tests

- Several different pathways depends upon classification and risk
  - Class III devices: PMA – Highest risk category, independent demonstration of safety and effectiveness
  - Class II devices: Comparative analysis
  - Traditional 510(k) – Substantial Equivalence, comparison to legally marketed predicate (same intended use, same/similar technological characteristics)
  - De Novo 510(k) – New or different, no predicate available but still can be class II
  - Class I devices: general regulatory controls (common to all devices)
  - EUA – Emergencies Only (Benefit-Risk in context of public health emergency)

- To be under review is to be vetted by the FDA's experts
  - Takes time
  - You do have some control
    - Submission organization
    - Prompt answers to questions

# COVID-19 Transition Plan Guidances



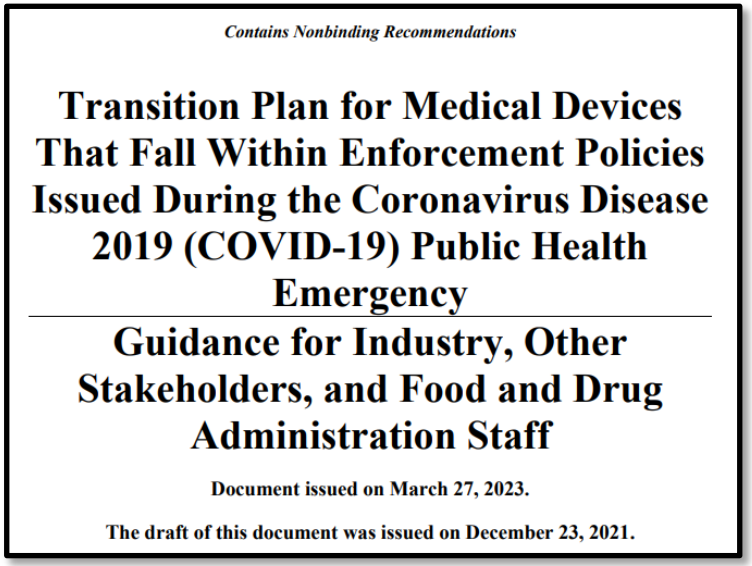
*Contains Nonbinding Recommendations*

**Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)**

**Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff**

Document issued on March 27, 2023.

The draft of this document was issued on December 23, 2021.



*Contains Nonbinding Recommendations*

**Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency**

**Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff**

Document issued on March 27, 2023.

The draft of this document was issued on December 23, 2021.

# COVID-19 Regulatory Terms

## Public Health Emergency (PHE)

- First declaration: January 31, 2020
  - Most recently renewed February 11, 2023
  - Set to expire on May 11,2023

## Emergency Use Authorizations (EUAs)

- An EUA remains in effect for the duration of the relevant EUA declaration, unless revoked by the FDA
- Over 950 EUAs have been issued for COVID-19 related products

## Enforcement Policies

- FDA issued 28 guidance documents describing enforcement policies
- "List 1" guidances will no longer be in effect 180 days after the end of the PHE

# COVID-19 Regulatory Transition Considerations

The FDA considered the unique circumstances around COVID-19

- Magnitude of the Pandemic
- Time for Effective Transition
- Non-Traditional Developers and Manufacturers
- Disruptions in Supply Chain

# Transition of Devices Under EUA

# Stakeholder Comments on Draft Transition Guidances

22 EUA Transition Guidance Comments Received

- Language and Definition Clarification
- Real-World Evidence
- Unique Device Identification Implementation
- Communication between Stakeholders and Manufacturers
- EUA Specific Comments:
  - Removal of interim labeling recommendations
  - Clarification of IVD policies, including CLIA, dual submissions and LDTs

# Comments Reflected in Published Transition Guidances

The FDA addressed these comments in the Transition Guidances

- Clarity on Terms
- Included Real-World Evidence
- Revised Labeling Recommendations
  - Physical or electronic copy acceptable
- Stakeholder Collaboration
- Additional Explanation and Examples
- EUA Specific
  - Removal of interim labeling requirement
  - Clarity on IVDs, including CLIA and LDTs

# General Transition Timeline

**+0 Days**

- Beginning of 180-Day Transition (EUA: HHS publication in Federal Registrar)

**+90 Days**

- Notification of intent for certain life sustaining/supporting devices

**+180 Days**

- Comply with legal requirements as applicable for specific device

# Transition Implementation Plan

Includes:

- Estimated number of devices in distribution
- Plan for Negative FDA Decision
  - Explanation of risk/benefit analysis for already distributed devices
  - Notification to stakeholders
  - Process and Timeline for restorations to cleared/approved configuration
  - Updating labeling
  - Maintenance Plan
- Plan for Positive FDA Decision
  - Process for addressing distributed devices
  - Notification to Stakeholders
  - Updating labeling

*Dates are hypothetical

# Case Study: Ventilator under EUA

**July 1***

- Notice of termination published in Federal Register
- Continue to comply with EUA conditions of authorization

**August 1***

- Submit Notification of Intent
- Continue to comply with EUA conditions of authorization

**January 1***

- Marketing submission accepted prior to this date
- **Intends to continue distribution**:
  - Continue distribution, complies with all legal requirements of 21 CFR 806, 807, 820
- **Intends to discontinue distribution:**
  - Ceases distribution

# Transition of Devices Under Enforcement Policy

# Key Changes From Draft to Final Guidance:

- **Transition start date is definitive – May 11, 2023;**
- **Each phase is more clearly defined:**
  - Phase 1: May 11, 2023 - August 9, 2023;
  - Phase 2: August 9, 2023 - November 7, 2023;
  - Phase 3: November 7, 2023 -
- **The final guidance contained a revised list of affected policies: 15 policies in the final guidance vs. 17 in the draft guidance:**
  - Two policies added:
    - Enforcement policy for Viral Transport Media During the COVID-19 PHE (Revised);
    - **Enforcement policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 PHE.**
  - Four policies removed:
    - Quality standards of the Mammography Quality Standards Act;
    - Non-invasive remote monitoring devices used to support patient monitoring;
    - **Face masks and barrier face coverings;**
    - Clinical electronic thermometers.

# Key Changes From Draft to Final Guidance (Cont.):

- Definition of "**already distributed**" – Devices that are finished, labeled and are in distribution in the U.S. supply chain or are in the possession of the end user.
- Definition of "**in distribution**" – Devices that are finished, labeled, and are no longer in the manufacturer's possession that are in transit to or held in a third party's device inventory not on behalf of the manufacturer, in a federal, state, or other governmental stockpile, or at a location where devices are then offered for direct sale to the end user.

# Enforcement Policies Affected: 15 Policies

**List 1**

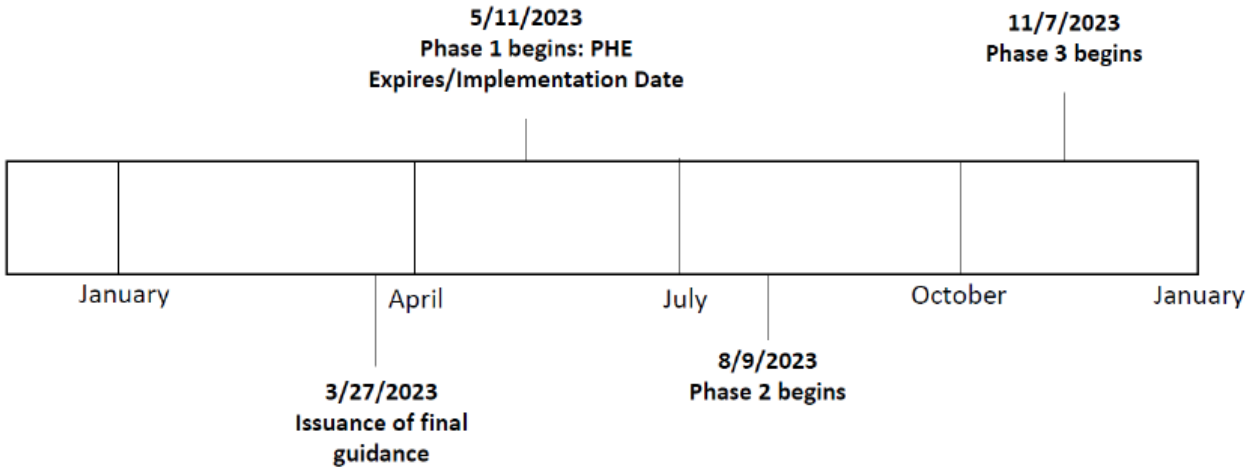
- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency[12]
- Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency[13]
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency[14]
- Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency[15]
- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency[16]
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the COVID-19 Public Health Emergency[17]

# Enforcement Policies Affected (Cont.):

- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 Public Health Emergency[18]
- Enforcement Policy for Infusion Pumps and Accessories During the COVID-19 Public Health Emergency[19]
- Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency [20]
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency[21]
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the COVID-19 Public Health Emergency[22]
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency[23]
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the COVID-19 Public Health Emergency[24]
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the COVID-19 Public Health Emergency (Revised)[25]
- Enforcement Policy for Viral Transport Media During the COVID-19 Public Health Emergency (Revised)[26]

# Transition Plan – A Phase Approach

A timeline for this process is provided in Figure 1.



# Transition Plan - A Phase Approach (Con't)

- **Phase 1**: **Implementation date to 90 days thereafter (5/11/2023 – 8/9/2023)**
  - Manufacturers should start complying with regular regulatory requirements:
    - Comply with adverse event reporting requirements under 21 CFR Part 803;
    - Comply with reporting of corrections and removals under 21 CFR Part 806;
    - Comply with establish registration and product listing under 21 CFR Part 807 Subpart B-D, if continued distribution is intended;
- **Phase 2: 90 days to 180 days post-implementation (8/9/2023 – 11/7/2023)**
  - Submit **Notification of Intent** for certain reusable life-sustaining/life-supporting devices;
  - Submit marketing submission and have FDA accept the submission by end of phase 2 if continued distribution is intended;
    - Should include a **transition implementation plan**.
- **Phase 3: 180 days after implementation date (11/7/2023 - )**
  - All 15 enforcement policies will expire;
  - If manufacturer intends to continue distributing devices:
    - Marketing submission has been made and accepted by FDA and FDA has not made final decisions on the submission;
    - Updated labeling should be provided to distributors and end-users;
  - If manufacturer does not intend to continue distributing devices:
    - Distribution ceases;
    - Work with FDA on disposing already distributed devices;
    - Continued use beyond transition depends on types of devices.

# Notification of Intent: Certain Reusable Life-Sustaining/Life-Supporting Devices

**Table 1**

| Product Code | Device Type | Classification Regulation |
|---|---|---|
| BSZ | Gas-machine, anesthesia | 21 CFR 868.5160 |
| CAW | Generator, oxygen, portable | 21 CFR 868.5440 |
| BTT | Humidifier, respiratory gas, (direct patient interface) | 21 CFR 868.5450 |
| QAV | High flow/high velocity humidified oxygen delivery device | 21 CFR 868.5454 |
| CBK | Ventilator, continuous, facility use | 21 CFR 868.5895 |
| MNT | Ventilator, continuous, minimal ventilatory support, facility use | |
| NOU | Continuous, ventilator, home use | |
| MNS | Ventilator, continuous, non-life-supporting | |
| ONZ | Mechanical ventilator | |
| BTL | Ventilator, emergency, powered (resuscitator) | 21 CFR 868.5925 |

# Beyond Transition – Continued Distribution is Intended:

- **Continued distribution is allowed if:**
  - A market submission has been submitted and accepted by FDA before end of phase 2;
  - FDA has not taken a final action on the marketing submission.
- **While the devices are under FDA review, FDA does not intend to object to the devices not complying with certain regulatory requirements:**
  - Unique Device Identification (UDI) requirements (21 CFR Part 801 Subpart B);
  - Applicable labeling requirements (21 CFR Part 801)
- **Manufacturer receives FDA positive decision:**
  - Continue distributing devices;
  - Provide updated labeling;
- **Manufacturer receives FDA negative decision:**
  - Ceases distribution;
  - Work with FDA to dispose already distributed devices;
  - Continued use allowed under certain circumstances (see next slide for details).

# Beyond Transition – Continued Distribution is Not Intended, FDA Does Not Intend to Request Immediate Recall If:

**For devices that were already distributed before the end of the transition (EUA termination date or end of Phase 2)**

| | |
|---|---|
| Single-use devices, non-LS/LS | • May be used by the end user prior to the product expiration date |
| Reusable, non-LS/LS | • May be used if they are:<br>  • Restored to FDA-cleared/approved version, **OR**<br>  • Have a physical and/or electronic copy of updated labeling that accurately describes the product features and states that device lacks FDA clearance, approval, or authorization |
| Reusable, LS/LS | • May be used if they are restored to FDA-cleared/approved version, **OR**<br>• **If not restored**, a physical and/or electronic copy of updated labeling that accurately describes the product features and that device lacks FDA clearance, approval, or authorization should be provided, and **such devices are not used** |

# Example 1: a 510(k) cleared fetal doppler modified under enforcement policy for non-invasive fetal and maternal monitoring devises:

**Phase 1(May 11, 2023)**

- Manufacturers should comply under 21 CFR Parts 803 (medical device reporting), 806 (reports of corrections and removals), and 820 (quality system regulation).

**Phase 2 (August 9, 2023)**

- Update existing listing under 21 CFR Part 807 Subparts B-D, as applicable (as an indication of intent to continue distribution beyond transition);
- Submit a marketing submission to FDA, including a "Transition Implementation Plan" for already distributed fetal dopplers in the case of a positive decision and in the case of a negative decision on the marketing submission;

**Phase 3 (November 7, 2023)**

- Marketing submission accepted and manufacturer has not received FDA final decision:
  - **Intends to continue distribution**:
    - Continue distribution, complies with all legal requirements of 21 CFR 806, 807, 820
    - Provide updated labeling
- Manufacturer receives a positive decision from FDA – continue distribution with updated labeling;
- Manufacturer receives a negative decision from FDA – restores to FDA-cleared version; ceases distribution of modified devices.

# Example 2: a 510(k) cleared diagnostic x-ray system modified to become portable and falls within the enforcement policy for imaging systems:

| | |
|---|---|
| **Phase 1(May 11, 2023)** | • Manufacturers should comply under 21 CFR Parts 803 (medical device reporting), 806 (reports of corrections and removals), and 820 (quality system regulation). |
| **Phase 2 (August 9, 2023)** | • Update existing listing under 21 CFR Part 807 Subparts B-D, as applicable (as an indication of intent to continue distribution beyond transition);<br>• Submit a marketing submission to FDA, including a "Transition Implementation Plan" for already distributed products in the case of a positive decision and in the case of a negative decision on the marketing submission; |
| **Phase 3 (November 7, 2023)** | • Marketing submission accepted and manufacturer has not received FDA final decision:<br>  • **Intends to continue distribution**:<br>  • Continue distribution, complies with all legal requirements of 21 CFR 806, 807, 820<br>  • Updated labeling provided<br>• Manufacturer receives a negative decision from FDA – needs to update device's labeling to reflect current regulatory status; engage in discussion with FDA for already distributed devices. |

## Example 3: A 510(k) cleared ventilator modified to make material changes to components in the gas pathway to accommodate supplier shortage and falls within enforcement policy for ventilators and accessories and other respiratory devices:

| | |
|---|---|
| **Phase 1(May 11, 2023)** | • Manufacturers should continue to comply under 21 CFR Parts 803 (medical device reporting), 806 (reports of corrections and removals), and 820 (quality system regulation). |
| **Phase 2 (August 9, 2023)** | • Update existing listing under 21 CFR Part 807 Subparts B-D, as applicable (as an indication of intent to continue distribution beyond transition);<br>• Submit a Notification of Intent;<br>• Submit a marketing submission to FDA, including a "Transition Implementation Plan" for already distributed products in the case of a positive decision and in the case of a negative decision on the marketing submission; |
| **Phase 3 (November 7, 2023)** | • Marketing submission accepted and manufacturer has not received FDA final decision:<br>  • **Intends to continue distribution**:<br>  • Continue distribution, complies with all legal requirements of 21 CFR 806, 807, 820<br>• Manufacturer receives a positive decision from FDA – continue distribution with updated labeling; communicates with users, apprising them with regulatory status and providing updated electronic labeling. |

## Example 4: A new telethermographic system that has not been FDA-cleared and is intended for adjunctive diagnostic screening by providing an initial body temperature assessment for triage use, falls within enforcement policy for telethermographic systems:

| | |
|---|---|
| **Phase 1(May 11, 2023)** | • Manufacturers should continue to comply under 21 CFR Parts 803 (medical device reporting), 806 (reports of corrections and removals), and 820 (quality system regulation). |
| **Phase 2 (August 9, 2023)** | • Update existing listing under 21 CFR Part 807 Subparts B-D, as applicable (as an indication of intent to continue distribution beyond transition);<br>• Submit a marketing submission to FDA, including a "Transition Implementation Plan" for already distributed products in the case of a positive decision and in the case of a negative decision on the marketing submission; |
| **Phase 3 (November 7, 2023)** | • Marketing submission accepted and manufacturer has not received FDA final decision:<br>  • **Intends to continue distribution**:<br>  • Continue distribution, complies with all legal requirements of 21 CFR 806, 807, 820<br>• Manufacturer receives a negative decision from FDA – ceases distribution; communicates with FDA regarding device disposition. |

# Resources for Assistance:

- FDA's final guidance document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease
- FDA's webinar on final guidance transition plans: https://www.fda.gov/media/167168/download
- FDA's Q-Submission program: https://www.fda.gov/media/114034/download

# Change of Legal Landscape

# Changes to Liability Protection - The Public Readiness and Emergency Preparedness (PREP) Act

- The end of the COVID-19 public health emergency alone does not automatically terminate PREP Act coverage for countermeasures;
- Secretary of the HHS will issue an amendment to the declaration under PREP Act for continued coverage of certain medical countermeasures after the transition period ends;
- A Fact Sheet is published on FDA website, indicating continued coverage for vaccines and tests: https://www.hhs.gov/about/news/2023/04/14/factsheet-hhs-announces-amend-declaration-prep-act-medical-countermeasures-against-covid19.html
- No mention of other medical devices in the Fact Sheet;
- Manufacturers should closely monitor the release of the HHS PREP Act Amendment.

# Changes to Supply Chain and Demand:

- Supply chain disruption may stabilize;
- Demand may return to normal levels;
- Legal implications may arise related to contract and labor disputes;
- Manufacturers should reevaluate and adjust supply chain strategies to adapt to the changing market;
- Continued monitoring of regulatory requirements is crucial to ensure compliance with local and international laws.

# Changes to Telehealth And Remote Monitoring Devices:

- Stricter regulations governing telehealth and remote monitoring devices may evolve;
- Insurance coverage and reimbursement policies for telehealth and remote monitoring services may change;
- Manufacturers should closely monitor the changing regulation and adjust their products and services accordingly;
- Collaboration with healthcare providers and payers is essential to navigate and adapt to any changes in telehealth and remote monitoring policies.

# Frequently Asked Regulatory Questions

# Questions Asked of the FDA

FDA responses:

- During the transition period, the FDA is still reviewing EUA amendments.
- For single use devices after May 11 with no traditional submission, use up stock.  Product is good until the expiration date.
- Note that these policies are not for drug or vaccine products.  These are for products regulated by CDRH.
- For enforcement policies not listed in List 1, expect a successive policy.
- For product specific questions, the FDA recommends using the Q-Sub process.

# Key Takeaways - Regulatory

- Though the public health emergency is ending, the regulatory policy is different for different products. List 1 Enforcement Policy products will begin to transition on May 11, but EUA products will not begin their transition until HHS publishes notice in the Federal Registrar.

- The regulatory landscape will continue to change during this time of transition.  If desired, get your marketing submissions in quickly!

# Upcoming Webinar – IVD Focus

- April 26 – 12:05 to 1pm EST – In Vitro Diagnostics

**Save the Date:**

The FDA will hold a virtual town hall on the following dates from 12:05 p.m.-1 p.m. ET:

- April 26: Ad Hoc Town Hall on recently finalized COVID-19 Transition Guidances for Medical Devices

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# Thank You! Questions?