IMDRF International Medical Device Regulators Forum

# U.S. FDA UPDATE

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# DIGITAL HEALTH

## Software Precertification Program 2019 Mid-Year Update

- **Retrospective testing identified the feasibility of the Streamlined Review package along with the Excellence Appraisal summary to be sufficient to conduct a premarket review of SaMD.**

- **Additional companies can volunteer as test cases for prospective testing if they are planning to submit a SaMD de novo or 510k soon.**

- **Results from the Excellence Appraisals performed so far suggest that the elements identified in the model can be demonstrated and could provide a comprehensive view of an organization's capabilities but more appraisals need to be conducted and evaluated to reach firm conclusions.**

July 18, 2019 https://www.fda.gov/media/129047/download

# FINAL GUIDANCE

## Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions

- **Although considering the extent of uncertainty of benefits and risks is already a part of our benefit-risk decision-making, this guidance makes these considerations more transparent, consistent, and objectively defined through a rigorous, methodical approach.**

- **The guidance also provides illustrative examples of how the principles for considering uncertainty could be applied in the context of clinical evidence and when greater uncertainty could be appropriate, such as PMAs for Breakthrough Devices and PMAs for devices intended for small patient populations.**

August 29, 2019 https://www.fda.gov/media/115672/download

# FINAL GUIDANCE

## Humanitarian Device Exemption Program

- **This guidance provides updated information on the operational aspects of the HDE Program and describes how the FDA determines whether to approve a humanitarian device exemption application for a device that is meant to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States.**

- **FDA also issued an update to the Humanitarian Use Device (HUD) Designations guidance to align it with the annual patient population threshold for a HUD designation laid out in the 21st Century Cures Act. Manufacturers need to receive a HUD designation before submitting an HDE application.**

September 5, 2019 https://www.fda.gov/media/74307/download

# FINAL GUIDANCE

## Acceptance Review for De Novo Classification Requests

- **This guidance provides clarity about the De Novo pathway and explains the procedures and criteria the FDA will use to determine if a submitted De Novo classification request (De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review.**

- **This guidance also includes a De Novo Acceptance Checklist and a Recommended Content Checklist.**

September 6, 2019 https://www.fda.gov/media/116945/download

# FINAL GUIDANCE

## Special 510(k) Program

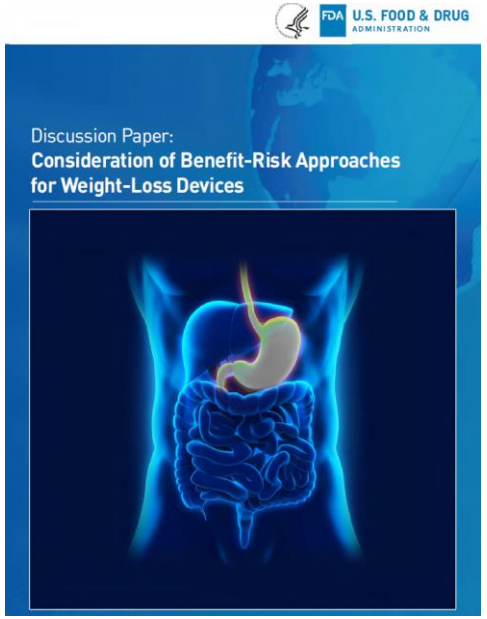
- **This guidance describes an optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed device.**

- **Under this pathway, rigorous design control procedure requirements produce highly reliable results that can form, in addition to other 510(k) content requirements, a basis for substantial equivalence.**

September 12, 2019 https://www.fda.gov/media/116418/download

# Discussion Paper

## Consideration of Benefit-Risk Approaches for Weight-Loss Devices




- **This discussion paper describes a concept the FDA is considering to assess the safety and effectiveness of weight-loss devices based on a sliding scale benefit-risk approach.**
- **This discussion paper also highlights areas where the FDA seeks input from stakeholders. A docket has been opened in the federal register for comments.**

September 5, 2019

https://www.fda.gov/media/130422/download?utm_campaign=2019-09-05%20Weight-Loss%20Devices%20Paper&utm_medium=email&utm_source=Eloqua

# THANK YOU