Center for Devices & Radiological Health: Lifecycle Products

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AAD FDA Symposium: Medical Devices

• The intent of this presentation is to present in brief specific actions by FDA CDRH information that is thought to be important.

• The information discussed represents material submitted to FDA appropriate for public discussion
Overview

• Definitions
• Lifecycle of devices
• Recent approved, granted, or cleared devices
Center for Devices & Radiological Health (CDRH)

• Mission is to protect and promote health
• Assure patients and providers have access to safe, effective, and high quality medical devices
• Accomplished through premarket and postmarket evaluations- Total Product Lifecycle (TPLC)
Premarket & Postmarket

• Review requests to research (clinical study) or market medical devices
• Medical Device Reporting (MDR) analysis
• Monitor compliance and surveillance programs for medical devices
• Designate and enforce good manufacturing practice regulations and performance standards for medical devices
## Device Regulatory Pathways

<table>
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<th>Class</th>
<th>Requirements</th>
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<tbody>
<tr>
<td><strong>Class I</strong></td>
<td>• Low risk&lt;br&gt;• Generally exempt from pre-market approval or clearance&lt;br&gt;• Subject to general controls and labeling requirements</td>
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<td><strong>Class II</strong></td>
<td>• Moderate risk/known risk&lt;br&gt;• Generally requires pre-market clearance (510(k))&lt;br&gt;• Subject to special controls in addition to general controls&lt;br&gt;• Need to demonstrate substantial equivalence to predicate (legally marketed) device</td>
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<td><strong>Class III</strong></td>
<td>• High risk&lt;br&gt;• Generally requires pre-market approval (PMA)&lt;br&gt;• Clinical Study under IDE&lt;br&gt;• Need to demonstrate reasonable assurance of safety and effectiveness</td>
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510(k) Pathway

• Premarket notification process
• Evaluation for substantial equivalence to a legally marketed predicate
• Intended Use
• Technological characteristics
Premarket Approval (PMA)

• Each device approval is on a case by case basis and based on data collected on that particular device
• Provide reasonable assurance that the device is safe and effective for its intended use and that it will be manufactured in accordance with current good manufacturing practice
DeNovo Pathway

• The Food and Drug Administration Modernization Act of 1997 (FDAMA) added the de novo classification option, which is also known as Evaluation of Automatic Class III Designation.

• Alternate pathway to classify novel devices of low to moderate risk. Devices that are classified through the de novo process may be marketed and used as predicates for future 510(k) submissions.
New Devices on the Market
Microneedling

• A microneedling device for aesthetic use is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics
DEN160029 SkinPen Precision System

The SkinPen Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years and older.
K180778 Exceed Microneedling Device

The Exceed is a microneedling device and accessories is intended for the treatment of wrinkles in Fitzpatrick skin types I, II and/or III in the following facial areas: glabellar frown lines, periorbital lines and cheek folds in adults aged 22 years or older.
K181740 CoolSculpting System

• The device is indicated for cold-assisted lipolysis (breakdown of fat) of upper arm, bra fat, back fat, banana roll, thigh, abdomen, and flank, or “love handles” in individuals with a Body Mass Index (BMI) of 30 or less.

• In addition, the device is intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2.
Dermal Fillers

• Approved Uses
P040024 Restylane Lyft with Lidocaine

• For injection into the subcutaneous plane in the dorsal hand to correct volume deficit in patients over the age of 21.

• Approved for use a cannula for cheek augmentation and correction of age related midface contour deficiencies in patients over the age of 21
P160042 Revanesse Versa+

• Injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults 22 years of age or more

• Addition of lidocaine to the formulation
510(K), PMA, and De Novo Databases

- 510(K) link

- PMA link

- De Novo link
Thank you