Device Classification

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Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices
Panel Meeting

July 29, 2022
What Is the Purpose of This Panel Meeting?

Discuss the available scientific evidence for Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers, which are currently regulated as Class III devices. You will be asked to recommend whether they should remain in Class III, or be reclassified to Class II as Computer-Aided Devices Which Provide Adjunctive Diagnostic Information About Lesions Suspicious for Melanoma
What Are the Device Classes?

• Classified based on controls necessary:
  — Class I (general controls)
  — Class II (special controls)
  — Class III (premarket approval)

A device should be placed in the lowest class whose level of control provides reasonable assurance of safety and effectiveness.
Class I Devices

- Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness
  - General controls include:
    - Registration and listing
    - Good manufacturing practices
    - Records and reports
    - Prohibitions against misbranding and adulteration
  - Class I devices typically do not require FDA premarket review prior to being marketed
Class I Devices

• Devices which cannot be classified into Class III:
  – Because they are not life-sustaining, life-supporting, of substantial importance in preventing impairment of human health, and
  – Because they do not present a potential unreasonable risk of illness or injury

• Devices which cannot be classified into Class II:
  – Because insufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness
Class II Devices

- Cannot be classified into Class I:
  - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness, and
  - for which there is sufficient information to establish special controls to provide such assurance

- Special controls can include:
  - Performance testing
  - Sterilization validation
  - Device-specific labeling requirements

- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
Class II Devices

• Class II devices typically require premarket notification to FDA (i.e., a 510(k)) prior to being marketed

• Companies must provide evidence in their 510(k) submissions of how the special controls were addressed
Class III Devices

• Cannot be classified into Class II because:
  – insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness, and
  – The devices:
    • are life-sustaining or life-supporting, or
    • are of substantial importance in preventing impairment of human health; or
    • present a potential unreasonable risk of illness or injury

• Class III devices typically require premarket approval (PMA) prior to being marketed
General controls sufficient?

Yes -> Class I

No -> Sufficient info for special controls?

Yes -> Class II

No -> Life supporting/sustaining/substantially important to human health?

Yes -> Class III

No -> Potential unreasonable risk?

Yes -> Class III

No -> No
What Is the Purpose of This Panel Meeting?

Discuss the available scientific evidence Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers, which are currently regulated as Class III devices. You will be asked to recommend whether they should remain in Class III, or be reclassified to Class II as Computer-Aided Devices Which Provide Adjunctive Diagnostic Information About Lesions Suspicious for Melanoma
Decision to start process is based on new information about the device, either on FDA’s own initiative or upon the petition of an interested person. The Agency considers intended uses which have been reviewed by the Agency.

- Publish a proposed order announcing our proposed classification and seeking public comment
  - Proposed order published 6/30/22
- Convene a panel meeting to discuss proposed classification
  - Completed today.
- Consider public comments and all available information, including panel recommendations, prior to issuing a final order
What We Need from the Panel

- Review and discuss available scientific evidence regarding safety and effectiveness of Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers

- Input and recommendations should include:
  - Identification of the risks to health presented by the device
  - Whether the device is life-supporting/life-sustaining, of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury
  - Whether sufficient information exists to develop special controls
  - Identification of special controls
  - Whether general controls alone are sufficient
What Will Happen After This Panel Meeting?

• FDA will consider the available evidence, including the input of this panel and the public comments

• FDA will issue a final order identifying the appropriate class
  – If Class I, devices may continue to be marketed
  – If Class II, existing devices may remain on the market provided they meet the designated special controls
  – If Class III, devices may continue to be marketed
FDA-Approved Computer-Aided Adjunctive Devices for Lesions Suspicious for Melanoma

Colin Kejing Chen, Ph.D.
Team Leader, Cancer Diagnostics and Treatment Devices
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices Panel Meeting

July 29, 2022
Two Approved PMA Devices

• **MelaFind (P090012)**
  • Reviewed at Panel Meeting 2010
  • Panel recommendations led to revisions in labeling
  • PMA approved 2011
  • First diagnostic device for melanoma – considered high risk
  • Not currently marketed

• **Nevisense (P150046)**
  • PMA approved 2017
  • First electrical impedance spectrometer for melanoma
MelaFind Device Description

- Non-invasive optical diagnostic device
- For use on lesions suspicious for melanoma
- Handheld imager applies light at 10 wavelengths (430-950nm)

Images with permission of Strata Skin Sciences
MelaFind Device Description

• Captures image at each wavelength
• AI/ML analyzes 3D morphological disorganization
• Output:
  – Melafind Positive = high grade dysplasia or melanoma
  – Melafind Negative = not high grade dysplasia or melanoma
  – Risk score (10-point scale)

Fink et al., JDDG 2017
MelaFind Intended Use

• Adjunctive information for dermatologist
• To aid decision to biopsy
• For pigmented lesions deemed suspicious for melanoma, with certain limitations
• Should NOT be used to confirm diagnosis of melanoma
• One element of overall clinical assessment
MelaFind Performance Testing

• Prospective, multi-center, blinded clinical study, 1383 patients
• Suspicious lesions photographed, MelaFind applied (output not visible)
• Dermatologist level of suspicion for MM recorded
• All study lesions were biopsied
• Pathology reviewed by ≥2 blinded central dermatopathologists
• No adverse events
MelaFind Performance Testing

• **Primary Aim 1:** Sensitivity ≥95% at 95% CI – met

<table>
<thead>
<tr>
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<th>Sensitivity</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>MelaFind</td>
<td>98.3%</td>
<td>94.1% - 99.7%</td>
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• **Primary Aim 2:** Specificity superior to study dermatologists – met

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<thead>
<tr>
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<th>Specificity</th>
<th>95% CI</th>
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<tr>
<td>MelaFind</td>
<td>10.6%</td>
<td>9.7% - 13.2%</td>
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<tr>
<td>Study Dermatologists</td>
<td>5.5%</td>
<td>4.5% - 7.3%</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td>5.1%</td>
<td>3.3% - 7.7%</td>
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</table>
MelaFind Performance Testing

- Reader study
- Compare sensitivity/specificity of MelaFind to providers
- Evaluated photos + dermoscopy + patient history

Results:

- Sensitivity, defined as correct decision to biopsy:
  - MelaFind 97%
  - Dermatologists 72% (p<0.0001)

- Specificity
  - MelaFind 9%
  - Dermatologists 51%
MelaFind 2010 Panel Discussion

• Risk of false negatives a significant safety concern

• Mitigations:
  – Device sensitivity
  – Labeling
  – Intended user: dermatologists trained in use of device
  – Intended use: to provide adjunctive information in decision to biopsy
  – Mandated post-approval study
Nevisense Device Description

- Electrical impedance spectrometer
  - Low electric current
  - Compares tissue impedance in lesion and perilesional skin
- AI/ML analysis of signals
- Output:
  - Score 1-10 (score 3.5+ considered "positive")
  - PPV/NPV of score

Images with permission of Scibase
Nevisense Intended Use

Similar to MelaFind:

• Adjunctive information for dermatologist
• To aid decision to biopsy
• For skin lesions deemed suspicious for melanoma, with certain limitations
• Should NOT be used to confirm diagnosis of melanoma
• One element of overall clinical assessment
Nevisense Study


- 1951 patients
- Investigators blinded to Nevisense output
- All study lesions biopsied, reviewed by 3 pathologists
- Safety: No serious adverse events

- Sensitivity  96.6%
- Specificity  34.4%
Summary

• MelaFind and Nevisense are computer-aided adjunctive diagnostic devices
• Intended Use specific to melanoma lesions and decision to biopsy
• FDA has cleared AI/ML-based diagnostic devices as Class II
  – Radiology, gastroenterology
  – Special controls drafted to mitigate risks
• AI/ML-based smartphone Apps (OUS) - low risk medical devices
Summary

• Propose to reclassify devices like MelaFind and Nevisense (adjuncts to melanoma diagnosis) from Class III PMA to Class II with Special Controls

• Panel will be asked whether these two devices should be reclassified

• Panel will be asked about the proposed Special Controls
Post-Market Safety and Effectiveness

Henry Lee, M.D.

Medical Officer, Light-Based Devices Team
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices
Panel Meeting

July 29, 2022
Methodology

• Post-Market safety and effectiveness:
  – Post-approval studies
  – Peer-reviewed literature
  – MDR, MAUDE, and recall databases
MelaFind Post-Approval Studies

• Assess MelaFind as adjunct to provider
  – Changed provider decision to biopsy 32.5%
  – Increased provider sensitivity by 2%
  – Specificity not assessed

• Standalone performance
  – MF+ output = 79% of lesions
  – Among MF+ lesions, 19% ultimately melanoma or high-grade lesions
• Hauschild et al (2014)
  – Impact of MelaFind on biopsy decisions
  – Increased dermatologists’ sensitivity from 69.5% to 78%
  – Decreased dermatologists’ specificity from 55.9% to 45.8%
Literature Review - MelaFind

- Winkelmann et al (2017)
  - Review of 7 studies evaluating MelaFind
  - Aggregate sensitivity improved from 70% to 88%
  - Aggregate specificity improved from 52% to 58%
  - Biopsy accuracy increased from 59% to 69%

Post-Market Reports

• MDR/MAUDE:
  – No adverse event reports for MelaFind or Nevisense

• Recall database:
  – Nevisense: none
  – MelaFind: one recall in 2015 – unapproved change in user interface
    • Affected 65 units
    • Addressed in PMA supplement
    • Ended May 4, 2016
Conclusion

• Premarket and postmarket evaluation of the MelaFind and Nevisense did not reveal significant safety concerns

• Class II with special controls will provide a reasonable assurance of safe and effective use of the devices and mitigate the risks to health
Device Classification and Reclassification Overview

Neil R.P. Ogden
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Center for Devices and Radiological Health
U.S. Food and Drug Administration

General and Plastic Surgery Devices Panel Meeting

July 29, 2022
FDA Device Classifications

CLASS I

CLASS II

CLASS III

Wire mesh stent in heart vessel (coronary artery)
Strike the Right Balance

CDRH 2015 strategic priority, “Strike the Right Balance Between Premarket and Post market Data Collection”

AI/ML technologies and their output are understood
   Training, Validation, False Positive, False Negative

Methodologies to assess performance of these devices are understood
   Sensitivity, Specificity, user improvement

Significant advances in AI/ML Technologies in recent years
   10,000s of publications on AI/ML in medical applications
AI/ML radiology and gastroenterology devices provide adjunctive diagnostic information for cancerous lesions under class II
Risks of Melafind & Nevisense type devices

- Technical review of the safety of the hardware and software
- Greater risk is the false negative output
- Additional risk of false positive output
Assessing Performance

Valid scientific evidence to describe the device performance.
• Clinical data
• Statistics
• Software V&V

Sensitivity and Specificity are high enough

Assuring the device technology is safe to use
• Biocompatibility
• Electrical
• Mechanical

Having appropriate Special Controls
Proposed Reclassification

• FDA is proposing to create a separate classification regulation for computer-aided devices for adjunctive diagnosis of lesions suspicious for melanoma that will be reclassified from class III to II.

• Reclassification of these device types will be prescription use.

• Premarket notification is necessary for these device types
Thank You
Proposed Reclassification and Regulatory Controls

Scott L. Kominsky, Ph.D.

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Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices
Panel Meeting

July 29, 2022
Proposed Reclassification and Regulatory Controls

Class II device:

- General and Special Controls are sufficient to provide reasonable assurance of safety and effectiveness
  - Probable benefits outweigh probable risks
  - No unreasonable risk of illness or injury
  - Clinically significant results in significant portion of target population
Special Controls

Potential Special Controls

– Performance standards
– Performance testing
– Post-market surveillance
– Patient registries
– Guidelines and recommendations
– Other appropriate actions deemed necessary by the Commissioner

Proposed Special Controls

– Performance testing
– Labeling requirements
## Proposed Special Controls

<table>
<thead>
<tr>
<th>Identified Risks to Health</th>
<th>Mitigation Measures</th>
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<tbody>
<tr>
<td>False negative or false positive results</td>
<td>• Clinical performance testing</td>
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<tr>
<td>↓</td>
<td>o May include:</td>
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<tr>
<td>Delayed diagnosis</td>
<td>o Standalone testing of sensitivity/specificity</td>
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<tr>
<td>Increased use of Healthcare resources</td>
<td>o Side-by-side comparison</td>
</tr>
<tr>
<td>Unnecessary medical procedures</td>
<td>o Reader study</td>
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<tr>
<td></td>
<td>o Provides improved assisted-read detection or diagnostic characterization of lesions suspicious for melanoma compared to characterization of lesions without the device</td>
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<tr>
<td>False negative or false positive results</td>
<td>• Non-clinical performance testing</td>
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<tr>
<td>↓</td>
<td>o Performs as intended under the anticipated conditions of use including testing of safety features intended to mitigate device-specific hazards</td>
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<tr>
<td>Delayed diagnosis</td>
<td>• Labeling</td>
</tr>
<tr>
<td>Increased use of Healthcare resources</td>
<td>o Detailed instructions for use</td>
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<tr>
<td>Unnecessary medical procedures</td>
<td>o Information on expected device performance on a dataset representative of the intended population</td>
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<tr>
<td>Improper device use / use error</td>
<td>• Labeling</td>
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<tr>
<td></td>
<td>o Intended patient population, anatomical sites, lesion types, compatible hardware/image acquisition</td>
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<td></td>
<td>o Foreseeable situations of device failure or poor performance</td>
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<tr>
<td>Delayed diagnosis</td>
<td></td>
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<tr>
<td>Increased use of Healthcare resources</td>
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<td>Improper device use / use error</td>
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<tr>
<td></td>
<td>o Description of device and interpretation of outputs</td>
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<td></td>
<td>o Required user qualifications, including training</td>
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<tr>
<td>Delayed diagnosis</td>
<td>• Human Factors Assessment</td>
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<tr>
<td>Increased use of Healthcare resources</td>
<td>o Intended users correctly use device following training</td>
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<tr>
<td>Unnecessary medical procedures</td>
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<thead>
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<tr>
<td>Device failure / Malfunction</td>
<td>- Non-clinical performance testing</td>
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<tr>
<td>↓</td>
<td>o Performs as intended under the anticipated conditions of use including testing of</td>
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<tr>
<td>Patient injury</td>
<td>safety features intended to mitigate device-specific hazards</td>
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<tr>
<td>Delayed diagnosis</td>
<td>- Software verification, validation, and hazard analysis</td>
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<tr>
<td>Increased use of Healthcare resources</td>
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<td>Unnecessary medical procedures</td>
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<thead>
<tr>
<th>Identified Risk to Health</th>
<th>Mitigation Measures</th>
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<tr>
<td>Electrical, thermal, mechanical, or light-related injury</td>
<td>• Electrical, mechanical, and thermal safety testing</td>
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<td></td>
<td>• Software verification, validation, and hazard analysis</td>
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<tr>
<td></td>
<td>• Labeling</td>
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<td></td>
<td>  o Instructions on appropriate use and maintenance</td>
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<td>  o Warnings and cautions to mitigate any device specific hazards, such as use near the eye</td>
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<tr>
<td>Interference with other devices</td>
<td>• Electromagnetic compatibility testing</td>
</tr>
<tr>
<td></td>
<td>o Ability of device to function safely and effectively in its intended electromagnetic environment, without introducing excessive electromagnetic disturbances that might interfere with other devices</td>
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<tbody>
<tr>
<td><strong>Adverse tissue reaction</strong></td>
<td>• Biocompatibility evaluation</td>
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<td></td>
<td>• Labeling</td>
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<td></td>
<td>o User qualifications needed for safe use</td>
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<td></td>
<td>o Instructions for device maintenance</td>
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<td></td>
<td>o Validated methods and instructions for reprocessing of any reusable components</td>
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<td><strong>Patient injury</strong></td>
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<td><strong>Infection and cross contamination</strong></td>
<td>• Sterilization validation</td>
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<td>• Shelf-life testing</td>
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<td>o Validated methods and instructions for reprocessing of any reusable components</td>
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Summary

Class II: General and Special controls are sufficient to provide reasonable assurance of safety and effectiveness

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<th>Identified Risks to Health</th>
<th>Special Controls</th>
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<tr>
<td>• False negative or false positive results</td>
<td>• Performance testing</td>
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<tr>
<td>• Improper device use / use error</td>
<td>• Labeling requirements</td>
</tr>
<tr>
<td>• Device failure / malfunction</td>
<td></td>
</tr>
<tr>
<td>• Electrical, thermal, mechanical, light-related injury</td>
<td></td>
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<tr>
<td>• Interference with other devices</td>
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<tr>
<td>• Adverse tissue reaction</td>
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<td>• Infection and cross contamination</td>
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<tr>
<td>Errors in patient management</td>
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<tr>
<td>Patient/User injury</td>
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FDA proposes that General and Special controls can provide reasonable assurance of safety and effectiveness
Questions for the Panel

Jianting Wang, Ph.D.

Biomedical Engineer, Acting Assistant Director
Light Based Energy Devices Team
Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
Food and Drug Administration

General and Plastic Surgery Devices
Panel Meeting

July 29, 2022
Question Overview

1) Health Risks of Skin Lesion Analyzers

2) Proposed Class II Device Criteria

3) Proposed Special Controls
Question 1: Health Risks of Skin Lesion Analyzers

• FDA has identified the following risks to health for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma:

  – False negative or false positive results
  – Use error / improper device use
  – Device failure / malfunction
  – Electrical, thermal, mechanical, or light-related injury
  – Interference with other devices
  – Adverse tissue reaction
  – Infection / cross contamination

• Please comment on whether this list completely and accurately identifies the risks to health presented by computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma.

• Please comment on whether you disagree with inclusion of any of these risks, or whether you believe that any other risks should be included in the overall risk assessment of this device type.
Question 2: Proposed Class II Device Criteria

• Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:
  – Insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND
  – if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

• A device should be Class II if:
  – general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND
  – there is sufficient information to establish special controls to provide such assurance.

• A device should be Class I if:
  – general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
  – insufficient information exists to:
    • determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
    • establish special controls to provide such assurance, BUT
      – is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
      – does not present a potential unreasonable risk of illness or injury.
Question 2: Proposed Class II Device Criteria

• FDA believes that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma. **If you disagree, please discuss how general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness for this device type.** General controls may include:
  - Prohibition against adulterated or misbranded devices,
  - Good Manufacturing Practices (GMP),
  - Registration of manufacturing facilities,
  - Listing of device types,
  - Record keeping, etc.

• FDA does not believe that computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma are “life supporting or life-sustaining, or of substantial importance in preventing impairment of human health.” **Do you agree with this assessment? If not, please explain why.**

• FDA does not believe that computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma present a “potential unreasonable risk of illness or injury” **Do you agree with this assessment? If not, please explain why.**

• FDA believes sufficient information exists to establish special controls for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma. Based on the information presented today, **please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness for this device type.**
Question 3: Proposed Special Controls

• FDA proposes that the following special controls would adequately mitigate the risks to health and provide reasonable assurance of safety and effectiveness for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma:
  – Clinical performance testing will demonstrate acceptable sensitivity and specificity.
  – Non-clinical performance testing will demonstrate acceptable sensitivity and specificity.
  – Non-clinical testing will demonstrate that the device operates as intended under the anticipated conditions.
  – Software validation and verification and cybersecurity testing will be completed in compliance with standards.
  – Thermal, mechanical, electrical, electromagnetic, and light safety testing will be completed in compliance with standards.
  – Biocompatibility, shelf life, and sterilization processes will be demonstrated to comply with standards.
  – Human factors testing and hazard analysis will be performed to acceptable standards.
  – Labeling will provide adequate information on device operation, intended use, intended users (dermatologists), intended patients, intended lesions (pigmented lesions suspicious for melanoma) and body sites, interpretation of output, caution against over-reliance on output, device maintenance and cleaning, and the known sensitivity and specificity of the device.

• Please discuss whether these special controls appropriately mitigate the identified risks to health of this device type, and whether you recommend additional or different special controls.