SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

NEUROLOGICAL DEVICES PANEL

June 4, 2021

Via Zoom Videoconference

Attendees:

Temporary Chair

Mary Jensen, M.D.
University of Virginia
Charlottesville, VA

Voting Member

Earl Ray Dorsey, M.D., M.B.A.
University of Rochester
Rochester, NY

Temporary Voting Members

Patrick Lyden, M.D.
University of Southern California
Los Angeles, CA

Julie Pilitsis, M.D., Ph.D.
Albany Medical College
Albany, NY

Stavropoula Tjoumakaris, M.D.
Jefferson University Hospitals
Philadelphia, PA

Karen Johnston, M.D., M.Sc.
University of Virginia
Charlottesville, VA

Sujay S. Galen, PT, Ph.D., F.H.E.A.
Byrdine F. Lewis College of Nursing and Health Professions
Atlanta, GA

Stephen McDavitt, PT, DPT, M.S., FAAOMPT, FAPTA
South College
Knoxville, TN

Rory A. Cooper, Ph.D.
University of Pittsburgh
Pittsburgh, PA

David J. Kennedy, M.D.
Vanderbilt University
Nashville, TN

Karen Anderson, M.D.
Georgetown University
Washington, D.C.

Wayne Goodman, M.D.
Baylor College of Medicine
Houston, TX

Heather Adams, Ph.D.
University of Rochester
Rochester, NY

Roberto Ortiz-Aguayo, M.D., M.M.M.
Children's Hospital of Philadelphia
Philadelphia, PA

James John McGough, M.D.
UCLA Health
Los Angeles, CA

Randy Dale Trumbower, Ph.D.
Emory University
Atlanta, GA

Industry Representative

Elijah Wreh, M.S.
Regulatory Affairs Manager
Zimmer Biomet

Consumer Representative

Veverly M. Edwards
Patient Safety Advocate/Affiliate Broker
First National Realty

Food and Drug Administration

Vivek Pinto, Ph.D.
Director, Division of Neuromodulation and Rehabilitation Devices

Xiaolin Zheng, Ph.D.
Director, Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices

Christopher Loftus, M.D.
Office Director (Acting), Neurological and Physical Medicine Devices

Patricio Garcia, M.P.H., CDR, USPHS
Designated Federal Officer

CALL TO ORDER

Panel Chairperson Mary Jensen, M.D., called the meeting to order at 9:02 a.m. She noted the presence of a quorum and affirmed that the Panel members had received training in FDA device law and regulations. She announced that the Panel would be discussing and making recommendations regarding the classification of attention task performance recorders, optical contour sensing devices, and plunger-like joint manipulators.

PANEL INTRODUCTIONS

Chairperson Jensen asked the Panel members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT

Patricio G. Garcia, M.P.H., CDR, USPHS, Designated Federal Officer, read the Conflict of Interest statement and reported that no conflict of interest waivers had been issued.

He introduced Elijah Wreh, M.S., as the Industry Representative.

TEMPORARY NON-VOTING MEMBER STATUS STATEMENT

CDR Garcia appointed Drs. Heather Adams, James McGough, and Roberto Ortiz-Aguayo as temporary non-voting members

CLASSIFICATION AND RECLASSIFICATION OVERVIEW

Megha Reddy explained the three medical device classifications and how they are determined. She then walked the Panel through the classification process for unclassified pre-amendments devices, clarified what input the Agency was seeking, and explained what the next steps will be before the issuance of a final rule.

FDA PRESENTATION

Classification of Attention Task Performance Recorders Under Product Code LQD

Mohua Choudhury, M.S., gave a device description and reviewed the indications for use, regulatory history, and clinical background of attention task performance recorders. She presented results from a literature review conducted for the purpose of gathering safety and effectiveness data for these devices. She reported that no adverse events were identified and that differences in the use of these products limits the ability to draw conclusions regarding effectiveness. She also provided background on medical device reports and recalls, noting that no MDRs were reported and that there were no recalls under this product code. She informed the Panel that patient discomfort, incorrect or inaccurate measurement of reaction time or other attention tasks, and incorrect or inaccurate results have been identified as risks and that these risks are split into two different categories:

1. Attention task performance recorders intended to measure reaction time and associated patient performance in response to attention tasks only; and
2. Attention task performance recorders intended to aid in the assessment or diagnosis of specific diseases or conditions.

She stated that FDA believes these risks cannot be sufficiently mitigated by general controls and that Class II classification with special controls is recommended.

PANEL DISCUSSION/Q&A

James John McGough, M.D., offered the following points for consideration:

- The sensitivity and specificity of these tests are poor and can lead to missed or misdiagnosed cases.
- They are not a standalone measure.
- They've never been predictive of treatment outcome and are not particularly predictive of diagnosis.

He stated that he agrees with FDA's assessment and general recommendation.

Heather Adams, Ph.D., agreed and stated that she has never used these devices for the same reasons. She added that she is concerned about the potential for loss of privacy and unnecessary financial burden to patients and their families.

Dr. McGough emphasized that the tests are not really harmful, but that they are expensive and give a false sense of security.

Dr. Adams reiterated that there is not much added value in using them and recommended practice parameters published by the American Academy of Pediatrics to aid general practitioners in making their own overall diagnoses.

Roberto Ortiz-Aguayo, M.D., M.M.M., asserted that the primary risk is delayed treatment along with undue distress on families and financial hardship.

Jay Gupta, Assistant Director**,** Neurodiagnostic Devices Division of Health Technology 5 A, specified that these products are not intended to be used in the assessment of concussion, but only for the evaluation of ADHD and that any other use would be off label.

Jane Peng, Ph.D., explained that the sensitivity and specificity of the tests is low because ADHD is complex and is often accompanied by other comorbidities such as autism, anxiety, and learning disabilities. She asserted that final diagnoses should be based on overall assessments by clinicians with input provided by parents, schools, and the patients themselves.

Wayne Goodman, M.D., asked if the tests can be used to monitor treatment progression. Dr. McGough reemphasized that they are a secondary measure and that there are better ways of making those assessments. Dr. Adams advised that observation of functional changes in everyday settings is the best way to determine if patients are receiving any benefits.

Rory A. Cooper, Ph.D., recommended careful review of the informed consent

process, especially with respect to efficacy and confidentiality issues.

Mr. Gupta informed the Panel that evaluation of sampling frequency is included in bench testing of device accuracy in the 510(k) submission process.

FDA QUESTIONS

Ms. Choudhury read Question 1: FDA has identified the following risks to health for attention task performance recorders intended to (1) measure reaction time and associated patient performance in response to attention tasks and (2) aid in assessment or diagnosis of specific diseases or conditions.

- Risks to Health and Descriptions/Examples for Attention Task Performance Recorders Intended to Measure Reaction Time and Associated Patient Performance in Response to Attention Tasks, Without Aiding in Assessment or Diagnosis:

    - Identified Risk: Patient discomfort (e.g., visual or mental fatigue).
    - Description/Examples: Use of the devices can cause patient discomfort, such as visual or mental fatigue.

    - Identified Risk: Incorrect or inaccurate measurements of reaction time or other attention tasks.
    - Description/Examples: Use of the devices can result in incorrect or inaccurate measurements of reaction time or other attention tasks based on associated patient performance.

- Risks to Health and Descriptions/Examples for Attention Task Performance Recorders Intended to Aid in Assessment or Diagnosis of Specific Diseases or Conditions:

    - Identified Risk: Patient discomfort (e.g., visual or mental fatigue).
    - Description/Examples: Use of the devices can cause patient discomfort, such as visual or mental fatigue.

    - Identified Risk: Incorrect or inaccurate results leading to inaccurate assessment or delayed diagnosis, both of which could result in inappropriate therapy or delay in treatment.
    - Description/Examples:

        - A false positive result means that the device indicates the patient has the clinical condition or disease of interest, such as ADHD or be at risk of cognitive impairment, when in fact none is present.
        - A false negative result means that the device indicates the patient does not have the clinical condition or disease of interest, such as ADHD or be at risk of cognitive impairment, when in fact the clinical condition or disease is present.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of attention task performance recorders under product code "LQD." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these devices.

Chairperson Jensen summarized the Panel's previous discussion:

- The Panel concurs with the inclusion of the risks in the overall risk assessment of these devices.
- Other concerns identified by Panel members include potential loss of confidentiality or privacy, and financial burden.
- Also, given the nature of the tests, there is concern that there may be a risk of induced epilepsy.
- The Panel recommends that controls be put into place to ensure that data is confidential, that informed consent should be required, and that patients/families be made aware that they are assuming a potential financial liability to acquire data that may not be useful.

Ms. Choudhury read Question 2: 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

        I. 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

II. does not present a potential unreasonable risk of illness or injury.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for attention task performance recorders. Following are risk/mitigation tables, which outline the identified risks to health for this device type and the recommended controls to mitigate the identified risks, delineated by intended use:

Risk/mitigation recommendations for attention task performance recorders intended to measure reaction time and associated patient performance in response to attention tasks only, without aiding in assessment or diagnosis:

- Identified Risk: Patient discomfort (e.g., visual or mental fatigue).
- Recommended Mitigation Measure: Labeling

- Identified Risk: Incorrect or inaccurate measurements of reaction time or other attention tasks.
- Recommended Mitigation Measures:
  - Non-clinical performance testing
  - Software verification, validation, and hazard analysis
  - Labeling

Risk/mitigation recommendations for attention task performance recorders intended to measure reaction time and associated patient performance in response to attention tasks:

- Identified Risk: Patient discomfort (e.g., visual or mental fatigue).
- Recommended Mitigation Measure: Labeling

- Identified Risk: Incorrect or inaccurate results leading to inaccurate assessment or delayed diagnosis, both of which could result in inappropriate therapy or delay in treatment.
- Recommended Mitigation Measures:
  - Clinical performance testing
  - Non-clinical performance testing
  - Software verification, validation, and hazard analysis
  - Labeling

a. Please discuss whether the identified special controls appropriately mitigate the identified risks to health for attention task performance recorders intended to measure reaction time and associated patient performance in response to attention tasks only, without aiding in assessment or diagnosis. Please also discuss whether additional or different special controls are recommended.

b. Please discuss whether the identified special controls appropriately mitigate the identified risks to health for attention task performance recorders intended to measure reaction time and associated patient performance in response to attention tasks for the aid in assessment or diagnosis of specific diseases or conditions. Please also discuss whether additional or different special controls are recommended.

A straw vote requested by the Chair indicated that the Panel agrees with the special controls identified by FDA.

Chairperson Jensen noted that the Panel recommends Class II classification with special controls.

Ms. Choudhury read Question 3: Please discuss whether you agree with FDA's proposed classification of Class II with special controls for attention task performance recorders. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

Chairperson Jensen confirmed that there is unanimous agreement among the Panel members that Class II is an appropriate classification.

FDA PRESENTATION

Classification of Optical Contour Sensing Devices Under Product Code LDK

Kiyana Weatherspoon gave a device description and reviewed the indications for use, regulatory history, and clinical background of optical contour sensing devices. She then presented results from a literature review conducted for the purpose of gathering safety and effectiveness data for these devices. She noted that the review was limited and was based on 10 relevant publications found in a search conducted specifically on brand names. She reported that the published literature suggests that optical contour sensing devices can replicate X-ray in the diagnosis of scoliosis and that they minimize radiation exposure. She also provided background on medical device reports and recalls, noting that no MDRs were identified and that there were no recalls. She informed the Panel that device failure or malfunction and use error, which can lead to inaccurate results and diagnosis, have been identified as risks; that FDA believes they can be sufficiently mitigated by general controls; and that Class I classification is recommended.

PANEL DISCUSSION/Q&A

Julie Pilitsis, M.D., Ph.D., observed that the devices are low risk and would minimize radiation exposure for patients who are frequently tracked.

David J. Kennedy, M.D., remarked that they are not accurate enough for following, diagnosing, or surgical planning and are not typically used by scoliosis surgeons. He explained that they are used on patients who are being treated for postural abnormalities for the purpose of tracking their progress.

Stavropoula Tjoumakaris, M.D., stated that efficacy has not been established and

that they should not replace standard of care. She surmised that they could possibly help in decreasing the frequency of X-rays while still maintaining standard of care in between.

Chairperson Jensen noted that another potential risk could be loss of confidentiality since software is involved.

FDA QUESTIONS

Ms. Weatherspoon read Question 1:

FDA has identified the following risks to health for optical contour sensing devices:

- Identified Risk: Device failure/malfunction leading to inaccurate results and diagnosis.
- Description/Examples: Device error may present inaccurate results to the user, leading to misdiagnosis, inadequate or improper patient management, or worsening of the condition.

- Identified Risk: Use error leading to inaccurate results and diagnosis.
- Description/Examples: User error may present inaccurate results to the user, leading to misdiagnosis, inadequate or improper patient management, or worsening of the condition.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of optical contour sensing devices under product code "LDK." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these devices.

Chairperson Jensen noted that the Panel agrees with the identified risks and would also include the possibility of inappropriate data breach.

Ms. Weatherspoon read Question 2: 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

    I. 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
    II. does not present a potential unreasonable risk of illness or injury.

FDA does not believe that special controls will be required for optical contour sensing devices under product code "LDK" and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness for these devices. As such, FDA believes that Class I is the appropriate classification for optical contour sensing devices under product code "LDK."

Please discuss whether you agree with FDA's proposed classification of Class I with general controls for these devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

Chairperson Jensen noted that the Panel does not believe special controls are needed and agrees that Class I classification is appropriate.

FDA PRESENTATION

Classification of Plunger-Like Joint Manipulators Under Product Code LXM

Kaitlin Olsen, M.S., gave a device description and reviewed the indications for use, regulatory history, and clinical background of plunger-like joint manipulators. She then presented results from a literature review conducted for the purpose of gathering safety and effectiveness data for these products. She noted that a total of seven articles were selected for review based on their relevance to the reported safety and/or effectiveness of these devices. She noted that minimal safety risks were disclosed in the literature with three of the seven studies reporting mild and transient adverse events, and that four studies saw statistically and/or clinically significant reduction in neck pain. She also provided background on medical device reports and recalls, noting that five relevant MDRs and one Class II recall were identified. She informed the Panel that adverse tissue reaction, electric shock or burn, pain, discomfort, and tissue injury have been identified as risks; that FDA believes that these risks cannot be sufficiently mitigated by general controls; and that Class II classification with special controls is recommended.

PANEL DISCUSSION/Q&A

Randy Dale Trumbower, Ph.D., stated that the efficacy of the devices is weak and that the potential for paralysis is his biggest concern. He surmised that it is not device failure alone that contributes to the negative effects.

Chairperson Jensen noted that there was not much data about the context in which the complications occurred and that in some cases in the studies, treatment consisted of a device plus manipulation. She acknowledged that the occurrence of hearing loss causes her concern about the possibility of vertebral artery dissections, and requested additional data about patients who had neurological disturbances post-treatment.

Dr. Tjoumakaris pointed out that there is a misconception that these devices are safer for manipulation, and that vertebral dissection could be flow-limiting or lead to posterior circulation infarcts, hearing loss, paresthesia, or even worse conditions. She stressed that a warning about vascular injury with life-threatening complications should be added to the indications and that major safety concerns should be addressed before even approving the device for physicians.

Stephen McDavitt, PT, DPT, M.S., FAAOMPT, FAPTA, stated that there should be proper screening and that people who perform these treatments should be qualified, not just licensed.

Patrick Lyden, M.D., pointed out that the devices are intended to be used in spinal manipulation or adjustment and that the typical outcome of dissections that he has seen are significant neurological disability or death due to basilar occlusion. He asserted that the only reasonable classification is Class III because there is no data to determine the frequency of these outcomes and that it would provide the means for obtaining more information.

Dr. Cooper remarked that the device is really a handheld robot and that people should be properly trained to use it.

Dr. Pilitsis agreed. She concluded that different sets of controls for the cervical spine and the lumbar spine would probably be appropriate.

Earl Ray Dorsey, M.D., M.B.A., pronounced that these devices pose more harm than benefit and that they should be contraindicated for use in the neck. He insisted that if they remain on the market, they should be Class III and used only for the lower back.

FDA QUESTIONS

Ms. Olsen read Question 1: FDA has identified the following risks to health for plunger-like joint manipulators:

- Identified Risk: Adverse tissue reaction
- Description/Examples: This can result from use of device materials that are not biocompatible.

- Identified Risk: Electric shock or burn
- Description/Examples: This can result from electrical failure or malfunction.

- Identified Risk: Pain
- Description/Examples: This risk could be due to a mechanical, electrical or software malfunction causing device failure. Types of pain include neck pain, radiating pain, and mid-back pain.

- Identified Risk: Discomfort
- Description/Examples: This risk can be caused by a mechanical, electrical, or software malfunction causing device failure. Types of discomfort include headache, fatigue, dizziness, stiffness, mild soreness, arm weakness, and arm numbness.

- Identified Risk: Tissue Injury
- Description/Examples: This risk could be due to a mechanical, electrical or software malfunction causing device failure. An example of tissue injury includes bruising from excessive force or pressure.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of plunger-like joint manipulators under product code "LXM." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these devices.

Chairperson Jensen noted that the Panel agrees and would include the following additional risks:

- injury to blood vessels
- stroke
- death
- disability
- spinal cord injury
- paralysis

Dr. Lyden commented that he is not sure that the relationship between manipulation and spinal cord trauma is as substantiated as it is with vascular injury.

Dr. Trumbower opined that in many cases secondary injuries can lead to spinal cord damage.

Chairperson Jensen replied that there is no data about the paralysis case to indicate whether or not it was a vascular or traumatic injury.

Karen Johnston, M.D., M.Sc., asked if paralysis could still be included as a potential risk.

Chairperson Jensen noted that the paralysis case has been associated with use of the device but there is no way of knowing its cause without more information.

Christopher Loftus, M.D., informed the Panel that what is usually referred to as vertebral injuries is actually cerebella or brain stem injuries.

Chairperson Jensen replied that if the anterior spinal artery comes off of a vessel, it can cause upper cervical cord injury.

Ms. Olsen read Question 2: 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

III. 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
IV. does not present a potential unreasonable risk of illness or injury.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for plunger-like joint manipulators. Following is a risk/mitigation table which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks.

Risk/mitigation recommendations for plunger-like joint manipulators under product code "LXM":

- Identified Risk: Adverse tissue reaction
- Recommended Mitigation Measure: Biocompatibility evaluation

- Identified Risk: Electric shock or burn
- Recommended Mitigation Measures:
  - Electromagnetic compatibility (EMC) testing
  - Electrical, mechanical, and thermal safety testing

- Identified Risk: Pain

- Recommended Mitigation Measures:
  - Electromagnetic compatibility (EMC) testing
  - Electrical, mechanical, and thermal safety testing
  - Non-clinical performance testing
  - Software verification, validation, and hazard analysis
  - Labeling

- Identified Risk: Discomfort
- Recommended Mitigation Measures:
  - Electromagnetic compatibility (EMC) testing
  - Electrical, mechanical, and thermal safety testing
  - Non-clinical performance testing
  - Software verification, validation, and hazard analysis
  - Labeling

- Identified Risk: Tissue injury
- Recommended Mitigation Measures:
  - Electromagnetic compatibility (EMC) testing
  - Electrical, mechanical, and thermal safety testing
  - Non-clinical performance testing
  - Software verification, validation, and hazard analysis
  - Labeling

Please discuss whether the identified special controls for plunger-like joint manipulators appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. The patient contacting components of the device must be demonstrated to be biocompatible.
2. Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.
3. Non-clinical performance testing must characterize the thrust force applied to the patient.
4. Software verification, validation, and hazard analysis must be performed.
5. Labeling must include:

    i. A warning that the device could cause pain, including neck pain, radiating pain, mid-back pain and tissue injury.
    ii. A warning that the device could cause discomfort, including headache, fatigue, dizziness, stiffness, mild soreness, arm weakness, and arm numbness.

Chairperson Jensen stated that the proposed special controls should include a warning that these devices could cause all of the identified potential complications.

Dr. Dorsey reiterated that they should be contraindicated for use in the neck.

Ms. Olsen read Question 3: Please discuss whether you agree with FDA's proposed classification of Class II with special controls for plunger-like joint manipulator devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

A straw vote requested by the Chair indicated that the Panel is in favor of Class III classification.

Sergio de del Castillo outlined the steps that would be taken as part of the PMA process.

Chairperson Jensen noted that there are significant safety issues, that there is very little efficacy data, and that the Panel believes these should be Class III devices.

FINAL COMMENTS

Elijah Wreh, M.S., Industry Representative, stated that his only concern is the impact that Class III classification will have on manufacturers.

Veverly M. Edwards, Consumer Representative**,** stated that her concerns were covered and that she agrees with the Panel's decision.

ADJOURNMENT

Dr. Loftus thanked the Panel and the FDA staff members.

Chairperson Jensen also thanked the FDA and adjourned the meeting at 11:48 a.m.

I certify that I attended this meeting on June 4, 2021 and that these minutes accurately reflect what transpired.

James P. Swink -S

Digitally signed by James P. Swink -S
Date: 2021.07.19 10:29:43 -04'00'

Patricio Garcia, M.P.H., CDR, USPHS
Designated Federal Officer

I approve the minutes of this meeting as recorded in this summary.

/S/

Mary Jensen, M.D.
Chairperson

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