SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL

September 9, 2020

Via Teleconference

Attendees:

Chairperson

Harvey E. Smith, M.D.
University of Pennsylvania School of Medicine
Philadelphia, PA

Voting Members

Maureen A. Finnegan, M.D.
University of Texas
Dallas, TX

Brent A. Blumenstein, Ph.D.
Trial Architecture (TriArc) Consulting
Washington, D.C.

Lynda J-S Yang, M.D., Ph.D.
University of Michigan
Ann Arbor, MI

Jeremy L. Gilbert, Ph.D.
Clemson University
Charleston, SC

Temporary Non-Voting Members

Karla V. Ballman, Ph.D.
Weill Cornell Medical College
New York, NY

Dirk H. Alander, M.D.
Geisinger Health System
Danville, PA

Benjamin Elder, M.D. Ph.D.
Mayo Clinic College of Medicine and Science
Rochester, MN

Glenn B. Pfeffer, M.D.
Cedars-Sinai Medical Center
Los Angeles, CA

Edward Ebramzadeh Abrams, Ph.D.
UCLA Orthopaedic Institute for Children
Los Angeles, CA

Colonel Patrick M. Osborn, M.D.
San Antonio Military Health System
Fort Sam Houston, TX

Frank R. Lewis, Jr., M.D.
American Board of Surgery
Philadelphia, PA

Hobart W. Harris, M.D.
University of California, San Francisco
San Francisco, CA

Industry Representative

Stacey Bonnell, M.B.A., RAC
DePuy Synthes
West Chester, PA

Patient Representative

Joseph P. O'Brien, M.B.A.
National Scoliosis Foundation
Stoughton, MA

Consumer Representative

Amy Price, D.Phil.
Stanford University
Stanford, CA

Food and Drug Administration

James Swink
Designated Federal Officer

Captain Raquel Peat, Ph.D., M.P.H., USPHS
Director, OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CALL TO ORDER

Panel Chairperson Harvey E. Smith, M.D., called the meeting to order at 8:06 a.m. He introduced Captain Raquel Peat, Director of OHT6, who gave introductory remarks. He then noted the presence of a quorum and affirmed that the Panel members had received training in FDA device law and regulations.

He announced that the Panel would be discussing and making recommendations regarding classification of semi-constrained toe (metatarsophalangeal) joint prostheses, intracompartmental pressure monitors, and intra-abdominal pressure monitoring devices.

PANEL INTRODUCTIONS

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

CONFLICT OF INTEREST STATEMENT

James P. Swink, Designated Federal Officer, read the Conflict of Interest Statement and reported that no conflict of interest waivers had been issued.

He introduced Stacey Bonnell as the Industry Representative and made general announcements regarding speaker identification and transcripts.

FDA PRESENTATION

Classification of Cemented Total First Metatarsophalangeal Replacement Devices

Michael Owens, M.S., provided a device description, reviewed the indications for use, and discussed the regulatory history of MTP devices.

Victoria Lilling, M.D., presented a clinical background on disease characteristics that affect the integrity of MTP joints, discussed currently available treatments, and summarized findings from a literature review. She noted that effectiveness for relief of pain or restoration of motion had mixed results with some reports showing higher adverse event rates and notable revision rates due to pain and loosening.

Mr. Owens highlighted the advantages and limitations of medical device reports, identified risks to health, and looked at potential mitigation strategies. He informed the Panel that FDA believes general controls are insufficient to provide a reasonable assurance of safety and effectiveness and recommends Class II classification for these devices.

Q&A

Maureen A. Finnegan, M.D., asked if the studies consisted mostly of low-demand patients or if they included younger and higher-demand patients. **Dr. Lilling** replied that all of the studies had a mixture of patients and that there was no specification of demand.

Frank R. Lewis, Jr., M.D., noted that no incidence data regarding the frequency of

complications was given. He asked how often they occurred. **Mr. Owens** acknowledged that this is one of the limitations of the MDR reporting system and that the incidence rates in the literature is also limited. **Dr. Lilling** reiterated that there are no available specifications of incidence rates because that is not how the MAUDE database is set up.

Glenn B. Pfeffer, M.D., stated that these devices create a tremendous amount of suffering and should not be allowed to be put into human beings. He pointed out that the reason why the MAUDE database only has 40 patients in it is because most incidents are not reported. He also said that he sees failure of these types of implants on a regular basis. **Mr. Owens** replied that FDA is cognizant of the risks but felt that it could move forward with the proposed classification given that clinical data can be used as potential special controls. He affirmed that the purpose of the meeting is to hear the Panel's concerns about the risks and proposed mitigation measures.

Dr. Finnegan agreed with Dr. Pfeffer. She related that she knows from doing rounds that these devices are a problem. She stated that they belong in Class III.

Dirk H. Alander, M.D., also agreed. He stated that it is not a great operation, nor is it a great prosthesis to use.

Colonel Patrick M. Osborn, M.D., said that he is seeing these in increasingly younger patients. He cautioned that bone loss with cemented arthroplasty is going to be a disaster and that this will not be limited to low-demand patients. He added that they also should not be getting the devices.

Edward Ebramzadeh Abrams, Ph.D., observed that these devices are obviously also intended for use without cement because they have grit-blasted surfaces. He pointed out that it is well known that titanium alloy should never be used in conjunction with cement. He asked why the Panel is addressing only cemented devices. He also asked why titanium is being used, if cross-linked polyethylene has been considered in the design, and if any wear testing has been done. **Mr. Owens** explained that, because the focus is on classifying preamendments devices, the Agency is limited to the way they were utilized, which was with cemented use.

Jeremy L. Gilbert, Ph.D., expounded on the similarities of materials used in other types of devices and pointed out that what is being said about toe implants today is the same thing that could have been said about shoulder arthroplasty over a decade ago. He pointed out that the degradation products used in the devices may lead to adverse reactions, that the risks are not disconnected, and that a range of hazards arise because of the interaction between various components. He also noted that corrosion was not identified as a risk and that this is also an aspect of interplay. **Mr. Owens** agreed that corrosion is a risk for these types of devices and that it may have been omitted by accident.

PANEL DELIBERATIONS

Dr. Gilbert asked Dr. Pfeffer to expound further on the logistics and clinical performance of cemented and polyethylene metal implants. **Dr. Pfeffer** pointed out that these implants loosen but never really get a chance to wear. He explained that the cortico-cancellous ratio is very different than it is in the knee, which has an extremely high surface area. He went on to say that these events are not usually reported because it is not something that would be considered a design failure, but more of a bad indication with patients who have not received adequate informed consent.

Dr. Alander opined that one of the risks may be the relaxation of indications and that they should be more stringent.

Dr. Finnegan asked Dr. Pfeffer what salvage procedures can be done when the devices fail. **Dr. Pfeffer** explained that a huge amount of bone is removed for the initial implant and that fusions may seem to work at first but will, at some point, fracture. He added that many patients request amputation after two or three failed operations because of the pain. He also explained that this causes significant problems for the lesser metatarsal because the big toe is not bearing any weight.

Lynda J-S Yang, M.D., Ph.D., commented that there does not seem to be enough good quality data on these devices, which would warrant putting them in Class III.

Dr. Pfeffer agreed. He remarked that the literature on this is of little worth and that any new devices should be put through a rigorous PMA process.

Karla V. Ballman, Ph.D., remarked that she is puzzled at the lack of data and why these devices are out on the market.

Mr. Owens pointed out that pre- and post-market clinical data is one of the proposed mitigation measures.

Dr. Lewis commented that mitigation strategies of labeling and clinical information are almost meaningless due to the unanimous opinion of those who have experience with the devices and because of the complete lack of data. He asserted that Class III is the appropriate way to go.

Dr. Pfeffer asked Mr. Owens why he would want Class II classification of these devices.

Dr. Alander asked what the roadblock is in going to a Class III.

Mr. Owens replied that, if the risks and proposed mitigation measures are not adequate, it is a possibility.

Stacey Bonnell, M.B.A., RAC, Industry Representative, reminded the Panel of the definition of a Class III device, that they are life-supporting, life-sustaining, and of substantial importance to human health. She proffered that if there are appropriate special controls that can be applied, the Panel would then have to determine if the devices fit into the Class II designation of moderate risk.

Amy Price, D.Phil., Consumer Representative, stated that these are very high-risk devices that do impair human health and that it is not possible to do informed consent because there is not enough information. She further stated that the onus is on the manufacturers to design better devices that work, that the special controls are not sufficient, and that randomized trials are needed.

Dr. Gilbert asked how many of the currently marketed total joint arthroplasties are Class III devices.

Dr. Finnegan pointed out that significant risk of injury and interference with general health is also part of the Class III definition. She stressed that she is very concerned about off-label use and that there are no special controls that will prevent trouble with these devices.

Dr. Yang commented that not being able to walk is a significant aspect of health.

FDA QUESTIONS

Chairperson Smith read Question 1: Please comment on whether you agree with

inclusion of all of the risks in the overall risk assessment of cemented total first MTP joint implants under product code "LZJ." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these cemented total first MTP joint implants.

Dr. Gilbert suggested the addition of tribocorrosion as a risk, as well as recognition of the possibility of combined interactions.

Dr. Finnegan stated that she does not believe there is enough data to make a decision about the risks.

Drs. Price, Ebramzadeh, Ballman, Osborn, and **Gilbert** agreed.

Benjamin Elder, M.D., Ph.D., stated that he is in agreement with the comments put forth, especially those of Dr. Pfeffer and Dr. Finnegan.

Dr. Pfeffer opined that the major risks of chronic pain, implant failure, potential infection, and amputation is inclusive enough.

Brent A. Blumenstein, Ph.D., remarked that the absence of data makes it difficult to answer the question.

Dr. Alander commented that the risks presented are sufficient but suggested the inclusion of multiple surgeries, device removal, and possible amputation.

Dr. Lewis pointed out that the list does not convey any degree of severity or likelihood of occurrence with respect to what a patient might actually anticipate.

Hobart W. Harris, M.D., questioned why the devices are on the market. He remarked that there does not seem to be a very compelling case for their continued use.

Dr. Osborn stated that the list of complications should include significant bone loss.

Chairperson Smith summarized the Panel's response:

- Seven members felt that there is not enough data to respond to the question.
- The complication list is fairly broad but should include additional risks such as corrosion, conjoint interactions, significant risk of amputation, and loss of function.
- Concerns were raised regarding osteolysis and bone loss.
- Ambulation of the foot should be specifically noted.
- Emphasis should be placed on the relative severity of the complications and the likelihood of occurrence so that patients can make adequate informed consent decisions.

Chairperson Smith read Question 2: Please discuss whether the identified potential controls for cemented total first MTP joint implants appropriately mitigate the identified risks to health and whether additional or different controls are recommended.

In addition, please discuss the following in relation to the mitigation of the identified risks:

i. The risks associated with multiple secondary surgeries are particularly significant and possibly long-lasting. Please discuss how the risk of multiple secondary surgeries should influence the selection of cemented total first MTP joint implant

arthroplasty when considering the overall benefit and risk profile of the subject devices and comment on the recommended mitigations to address this risk.

ii. Given the apparently equivocal and low-quality data available in published literature, please comment on how the available evidence is used to determine the choice to use these devices in cemented total first MTP joint implants arthroplasty. As part of this discussion, please discuss the outcomes that provide clinically meaningful benefit and what types of evidence (such as clinical evidence) would be helpful to support mitigation of the identified risks.

Dr. Gilbert stressed the need for Level I clinical data. He stated that a prospective, randomized, blinded, controlled study should be required to assure safety and effectiveness.

Drs. Blumenstein, Ballman, and **Price** agreed.

Dr. Ballman remarked that Level I data should be required to show if there is any benefit.

Dr. Price emphasized that positive Level I elements are needed to ensure against putting the population at risk.

Dr. Pfeffer remarked that it is clear that Class III is more rigorous than Class II. He suggested that if Class III is the same as Class II, it should be done away with.

Joseph P. O'Brien, M.B.A., Patient Representative, commented that the potential harm is frightening. He emphasized that the utmost scrutiny is required on behalf of patients.

Dr. Finnegan pointed out that neither safety nor effectiveness have been proven.

Dr. Price theorized that the Panel would not want innovators to build on the same predicate because it is unsafe and ineffectual.

Dr. Lewis stated that additional controls of some type are definitely needed, that the risks associated with multiple surgeries are not adequately described, and that the deficiency of the data does not allow for a choice between the different devices.

The Panel members unanimously agreed with Dr. Lewis and indicated that both answers to the question is no.

Mr. O'Brien and **Dr. Price** also agreed.

Ms. Bonnell thanked the panelists for weighing in and keeping the prioritization on patient safety.

Chairperson Smith summarized the Panel's response:

- The risks are not well described, and additional clinical information is needed.
- Level I data is requested. If that is not feasible, some sort of postmarket assessment and review should be required.
- The data is inadequate.

Chairperson Smith read Question 3: 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 cemented total first MTP joint implants.

Based upon the information presented in the panel package and today's discussion, please discuss whether you agree with FDA's proposed classification of Class II with special controls for cemented total first MTP joint implants. If you do not agree with FDA proposed classification, please provide your rationale for recommending a different classification.

Dr. Finnegan disagreed with Class II classification. She stated that the device impairs human health and that it presents a potential unreasonable risk of illness or injury.

Drs. Yang, Elder, Blumenstein, Harris, and **Osborn** agreed.

Dr. Gilbert stated that the device should not be in Class II. He emphasized that a true demonstration of safety and efficacy is lacking.

Dr. Lewis agreed. He stated that the device is not appropriate for Class II, and the mitigation strategies do not adequately address the long-term risk and severity of complications.

Dr. Alander said that he disagrees with Class II classification due to the paucity of information.

Dr. Ballman agreed and added that she has concerns about the lack of efficacy.

Dr. Ebramzadeh remarked that he disagrees with Class II for all of the reasons stated.

Mr. O'Brien and **Dr. Price** indicated that they concur with the rest of the Panel members.

Ms. Bonnell stated that it appears that Class III is appropriate but general and special controls will suffice because of the inadequacy of the data.

Chairperson Smith summarized the Panel's response:

- There is unanimous disagreement with Class II classification; the rationale is based primarily on the lack of adequate data.
- There are also concerns regarding potential harm to patients.

FDA PRESENTATION

Classification of Intra-Compartmental Pressure Monitor Devices Under Product Code LXC

Peter Allen, M.S., discussed the intended use and indications for use, gave a device description, and reviewed the regulatory history. He noted that there is no regulation associated with the product code because these devices are currently unclassified.

Neil Barkin, M.D., gave an overview of the clinical background and treatment options. He identified trauma as the most common cause of compartment syndrome and emphasized that, without proper treatment, the consequences can be severe.

Mr. Allen summarized findings from a literature review and medical device reports.

He noted that 16 MDRs were reported from 1987 to the present and that the majority of the reports involved error messages or probe defects. He then focused the remainder of his discussion on risks and mitigations, the proposed classification, and special controls.

Q&A

Dr. Finnegan suggested the addition of user error as a mitigation.

Dr. Ebramzadeh asked for clarification regarding interference with other devices. **Mr. Allen** replied that it refers to electrical interference with devices that are attached to monitors or other equipment.

Dr. Price speculated as to whether clinical care instructions should be included.

Mr. O'Brien pondered whether the labeling would be helpful to someone who rarely sees compartment syndrome.

Dr. Barkin conjectured that someone who does not normally do these procedures would want a thorough explanation of how the device functions.

Dr. Ebramzadeh asked if there are any risks of tissue damage from the probe and if it varies among the different types of designs. **Mr. Allen** replied that not much has been seen in the literature about tissue damage. **Dr. Barkin** commented that compartment syndrome is much worse than any damage a small needle could produce.

FDA QUESTIONS

Chairperson Smith read Question 1: Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of the intracompartmental pressure monitor devices under product code "LXC".

In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these intracompartmental pressure monitor devices.

Dr. Alander stressed the importance of including specific instructions and references in the labeling to mitigate user error.

Mr. Allen specified that surgical techniques would be included in the labeling.

Dr. Harris suggested the inclusion of bruising and pain associated with the use of needles.

Dr. Barkin pointed out that compartment syndrome presents with either severe pain or very little pain. He remarked that, in either instance, discomfort from a needle would probably not be a major consideration.

Dr. Lewis commented that the procedure is complex, but risks from the device itself are minimal.

Dr. Barkin advised that there is some evidence that the measurement of perfusion pressure is a more reliable method.

Mr. Allen explained that the risk of burn or electrical issues was identified in some of the predicate submissions.

Chairperson Smith polled the Panel members for their responses.

Dr. Finnegan stated that user error should be added for people who seldom use these devices.

Drs. Yang, Ballman, Ebramzadeh, Alander, Pfeffer, **Elder** and **Gilbert** agreed.

Dr. Harris stated that the list seems to be excessive. He remarked that there is no reason to discuss electrocution or burning and that it is arguable that these devices would interfere with other equipment.

Dr. Gilbert agreed.

Dr. Lewis concurred that the identified risks are excessive. He pointed out that adverse tissue reaction is not a problem, that burns and electrical shock are highly unlikely, and that interference with other equipment would probably not occur because these devices are low DC.

Dr. Blumenstein declined to comment.

Chairperson Smith announced that **Dr. Osborn** had to leave the meeting and that, before doing so, he indicated that he agrees with the proposed classification and commented that acute compartment syndrome and clinical diagnosis must maintain a high level of suspicion.

Chairperson Smith summarized the Panel's response:

- There was one abstention.
- Two members felt that the risks are excessive, particularly with respect to device interference and the risk of electrical shock or burn.
- User error could pose a significant risk.
- A high level of attention to detail should be given to all four of the lower extremity compartments when measuring pressure.

Chairperson Smith read Question 2: Please discuss whether the following special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

1. Patient-contacting components of the device must be demonstrated to be biocompatible.
2. Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following must be conducted:

    - an assessment of the mechanical output specifications, including testing to validate the accuracy of the probe pressure measurement if applicable
    - mechanical safety testing to validate safeguards related to the pressure aspects of the device
    - electrical safety, thermal safety, and electromagnetic compatibility (EMC) of all electrical components of the device
    - software verification, validation, and hazard analysis

3. Validation testing must demonstrate the sterility of the final packaged device.
4. Validation of reprocessing instructions to demonstrate reusable or non-sterile

components of the device can be adequately cleaned and re-sterilized.

5. The labeling for the device must include the following:

   - importance of adequately cleaning probe tips
   - importance of accurate placement of the device
   - validated reprocessing instructions (cleaning, sterilization) for non-sterile and/or reusable devices
   - instructions for proper handling of electrical components

Dr. Alander reiterated that labeling should include accurate operating instructions.

Dr. Ballman agreed.

Dr. Harris suggested that user error would have to be added to the list so that it could then be addressed in the labeling with appropriate instructions.

Dr. Ebramzadeh asked if the labeling should address compartment-specific risks.

Chairperson Smith polled the Panel members for their responses.

Dr. Finnegan stated that the special controls are adequate if they incorporate the suggestions put forth by Drs. Alander and Harris.

Drs. Yang, Ballman, Ebramzadeh, Harris, Alander, Pfeffer, Elder, Lewis, and **Gilbert** agreed.

Dr. Blumenstein declined to comment.

Dr. Lewis remarked that the current specifications are excessive and that the device could even be in Class I.

Mr. O'Brien indicated that he agrees with Dr. Finnegan on Questions 1 and 2. He further stated that the recommendation put forth by Dr. Harris should be included.

Dr. Price agreed.

Ms. Bonnell stated that she agrees with the previous comments and that the recommendations for adequate instructions are appropriate.

Chairperson Smith summarized the Panel's response:

- There was one abstention.
- The remaining panelists unanimously agreed that the risk of user error should be added to the labeling.
- Concerns were raised about the anatomy of different compartments, which should be noted.
- Some members commented that the risks are excessive.
- One member observed that the device would be appropriate in Class I.

Chairperson Smith read Question 3: Please discuss whether you agree with FDA's proposed classification of Class II with special controls for intracompartmental pressure monitors. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

Dr. Blumenstein declined to comment.
The rest of the Panel members unanimously agreed with the proposed classification.

Chairperson Smith noted **Dr. Osborn's** previous indication of concurrence with Class II designation.
He then asked the representatives for their comments:

Mr. O'Brien remarked that user error and the recommendations regarding labeling instructions are important. He indicated that he agrees with the proposed classification.
Dr. Price also agreed.

Chairperson Smith summarized the Panel's response:

- There was one abstention.
- The remaining members unanimously agreed with Class II classification.

FDA PRESENTATION

Classification of Intra-Abdominal Pressure Monitoring Devices Under Product Code PHU

Cal F. Rabang, Ph.D., reviewed the intended use and indications for use, summarized the findings from medical device reports and a review of the literature, and identified associated risks and mitigations. He informed the Panel that FDA is recommending Class II classification and discussed the proposed special controls.

Q&A

Dr. Lewis noted that the only part of the device that contacts the patient is the Foley catheter. He asked why this is being treated as a separate device. **Dr. Rabang** explained that it is all one device with the catheter being a part of the tubing set.
Dr. Ebramzadeh asked who designs the protocols and procedures for mechanical testing. **Dr. Rabang** replied that it is up to the manufacturer.
Dr. Harris asked for a device description. **Dr. Rabang** explained that it consists of a Foley catheter connected to tubing for the purpose of providing displacement for pressure measurement.
Dr. Yang asked why this is separate and is not considered to be a Class II Foley catheter. **Dr. Rabang** reiterated that the catheter is connected to several components of tubing and that the device is sold as a complete system. **Mark Trumbore, Ph.D.,** further explained that the manufacturer has a different intended use for the device and that the Foley catheter is a part of it.

PANEL DELIBERATIONS

Dr. Gilbert suggested that some of the comments from the prior discussion would relate to this device.

Dr. Harris commented that there are issues regarding the proper standardization of pressure measurements.

Dr. Lewis stated that there are many similarities and many sources of error that relate to user practice. He stressed that the issues of user familiarity and performance are more important than just the device itself.

FDA QUESTIONS

Chairperson Smith read Question 1: FDA has identified the following risks to health for intra-abdominal pressure monitoring devices under product code "PHU" based upon FDA's review of literature, information available to FDA regarding the cleared devices, and the Manufacturer and User facility Device Experience (MAUDE) database:

- Adverse tissue reaction
- Infection
- Local tissue injury
- Incorrect patient diagnosis

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of the intra-abdominal pressure monitoring devices under product code "PHU".

In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of the intra-abdominal pressure monitoring devices.

Dr. Harris stated that there is no need for the inclusion of additional risks.

Dr. Finnegan suggested the inclusion of user error.

Dr. Gilbert agreed.

Dr. Ebramzadeh stated that the list is adequate.

Drs. Yang, Pfeffer, Ballman, and **Lewis** agreed.

Dr. Alander stated that the risks are adequate with the addition of potential user error. **Dr. Elder** indicated that he agrees.

Dr. Blumenstein declined to comment.

Ms. Bonnell stated that she agrees with the Panel and the previous comments.

Mr. O'Brien and **Dr. Price** concurred that the risks are adequate with the inclusion of user error.

Chairperson Smith summarized the Panel's response:

- There was general agreement among the Panel members that the risks are adequate.
- A significant subset indicated that user error should be included.
- There was one abstention.

Chairperson Smith read Question 2: Please discuss whether the following special

controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

- Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

  – Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use and maintain device integrity upon repeated actuation/measurements.
  – Performance testing should validate clinically relevant pressure range and ensure the pressure ranges used do not cause inadvertent damage to underlying tissue.
  – Performance testing must demonstrate proper function and accurate pressure measurement.

- The device must be demonstrated to be biocompatible
- Validation testing must demonstrate the sterility of the device.
- Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
- The labeling must include all adequate warnings/precautions and instructions regarding the proper placement and use of the device.

Dr. Ebramzadeh asked what the shelf life is and if the manufacturers should be obligated to specify it. **Dr. Rabang** replied that companies should identify the shelf life and be able to substantiate it. He indicated that it would be a part of the labeling**.**

Dr. Harris stated that the special controls are adequate and that appropriate instructions for use should be included in the labeling if user error is added as a risk**.**

Drs. Finnegan, Alander, Gilbert, Pfeffer, Elder, Ballman, and **Lewis** agreed.

Dr. Ebramzadeh stated that the list is adequate.

Dr. Yang agreed.

Dr. Blumenstein declined to comment.

Mr. O'Brien agreed that the special controls are adequate. He pointed out that the last bullet point does include instructions for use.

Ms. Bonnell stated that adequate instructions for use are part of general controls for all classifications.

Dr. Price agreed.

Chairperson Smith summarized the Panel's response:

- One member of the Panel abstained.
- The remaining members unanimously agreed.
- A significant subset indicated that there is concern regarding user error.
- The issue of shelf life was raised.

- The need for instructional labeling was discussed.
- One member noted that instructional labeling is generally included with all devices.

Chairperson Smith read Question 3: Please discuss whether you agree with FDA's proposed classification of Class II with special controls for intra-abdominal pressure monitoring devices.

If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

Dr. Blumenstein declined to comment.

The rest of the Panel members unanimously agreed with Class II classification.

FDA SUMMATION

Captain Raquel Peat, Ph.D., M.P.H., USPHS, affirmed that the Panel's recommendations will be taken into consideration for further steps.

She thanked Chairperson Smith, the Panel, and the presenters and participants for their contributions to the meeting.

ADJOURNMENT

Chairperson Smith declared the meeting adjourned.

Lieutenant Commander Randoshia Miller, MS, BSN, RN, thanked the audience for attending and expressed appreciation for the efforts of the Panel, presenters, FDA staff, and sponsor contributors for their efforts in implementing the second day of the meeting.

The meeting adjourned at 11:51 a.m.

I certify that I attended this meeting on September 9, 2020, and that these minutes accurately reflect what transpired.

_____/S/_____
James Swink
Designated Federal Officer

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

_____/S/_____
Harvey E. Smith, M.D.
Chairperson

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September 20, 2020