FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Brief Summary of the Orthopaedic and Rehabilitation Devices Panel Meeting
September 9, 2020

Introduction:

A meeting of the Orthopedic and Rehabilitation Panel of the Medical Device Advisory Committee was convened on September 9, 2020, to discuss and make recommendations regarding the classification of three unclassified, pre-amendments devices. In session I, the Panel was asked to discuss and make recommendations regarding the proposed classification of semi-constrained toe (metatarsophalangeal) joint prostheses to Class II (general and special controls). During session II, the Panel was asked to discuss and make recommendations regarding the proposed classification of intracompartmental pressure monitors to Class II (general and special controls). During session III, the Panel was asked to discuss and make recommendations regarding the proposed classification of intra-abdominal pressure monitoring devices to Class II (general and special controls).

Session I: Semi-Constrained Toe (metatarsophalangeal) Joint Prostheses

The Panel discussed the following FDA-identified risks to health for cemented total first metatarsophalangeal (MTP) joint implants under product code "LZJ":

1. Failure at the bone/implant interface (e.g., Lack of hallux purchase; Implant migration; Loosening of the prosthesis)
2. Fracturing of the metatarsal head or base of the proximal phalanx during implantation
3. Osteolysis or heterotopic ossification around the implant system
4. Sesamoid pathology
5. Recurrence of the hallux deformity
6. Painful/limited first MTP joint range of motion
7. Implant breakage or disassociation of components
8. Infection
9. Dislocation/Subluxation
10. Use Error
11. Adverse Tissue Reaction
12. MR induced migration and heating and image artifact
13. Multiple secondary surgeries as sequelae of device removal

The Panel noted that the available literature does not provide enough data to support that there is an understanding of all of the risks associated with this device type and therefore could not conclude that the identified list was complete. However, the Panel recommended adding corrosion, amputation, combined interaction, and transfer metatarsalgia (pain and inflammation in the ball of the foot) before or after failure to the list presented by the FDA. In general, the Panel expressed concerns regarding the significant risks associated with this device type.

The Panel discussed the identified potential controls for cemented total first MTP joint implants and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel reiterated concerns regarding the poor quality of the available literature and the inability to identify all of the risks associated with this device category.

Given the apparently mixed results and data available in published literature, the Panel was asked to comment on how the available evidence is used to determine the choice to use these devices in cemented total first MTP joint implant arthroplasty. The Panel stated that the literature evidence was poor and limited. However, there was a definitive conclusion from their review of the literature and their experience that there is a significant risk with use of this device category, and the Panel recommended strongly that significant regulatory oversight should be put in place. The Panel recommended rigorous studies in order support robust and informed data generation for use of this device due to insufficient information on the risks.

The Panel did not agree with FDA's proposed classification of Class II with special controls for cemented total first MTP joint implants. While not explicitly requested, there was a consensus that these devices should be classified as Class III.

Session II: Intracompartmental Pressure Monitors

The Panel commented on the inclusion of all of the risks in the overall risk assessment of intracompartmental pressure monitors under product code "LXC". The risks identified by the FDA included:

- Adverse tissue reaction
- Device malfunction
- Electrical shock or burn
- Interference with other devices
- Infection

The Panel was asked to discuss whether they agreed with the identified risks and whether any additional risks should be included in the overall risk assessment. The Panel agreed that the proposed risks were appropriate and emphasized that user-error may be the predominant risk and should be added to this list of identified risks. A few panel members commented that the risks of electrical shock/burn and interference (electrical) with other devices may be overstated, and rarely, if ever, expected to occur.

The Panel was asked to discuss whether the identified special controls for intracompartmental pressure monitors are appropriate to mitigate the identified risks to health and whether additional or different special controls are recommended. The Panel agreed that the proposed special controls were adequate to address the identified risks. For the additional risk of user-error, the Panel recommended that adequate labeling to instruct the end user on proper placement and use of the device be included as a special control.

The Panel concurred with FDA's proposed classification of Class II with special controls being appropriate for these devices, at least one Panel member suggested FDA even consider Class I.

Session III: Intra-Abdominal Pressure Monitoring Devices

The Panel was asked to comment on whether they believed that the inclusion of all of the risks in the overall risk assessment of for intra-abdominal pressure monitoring devices under product code "PHU" is sufficient or if they believed that additional risks should be considered. The identified risks are as follows:

- Adverse tissue reaction
- Infection

- Local tissue injury
- Incorrect patient diagnosis

The Panel was asked to discuss whether the identified special controls for intra-abdominal pressure monitoring devices appropriately mitigate the identified risks to health and whether additional or different special controls are recommended. The panel agreed that the proposed risks were appropriate. Some panel members suggested the addition of user error as an identified risk, with a recommendation for adequate end user labeling to be included as a special control.

The Panel agreed with FDA's proposed classification of Class II with special controls for intra-abdominal pressure monitoring devices.

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