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

Brief Summary of the Orthopaedic and Rehabilitation Devices Panel Meeting September 8, 2020

Introduction:

A meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee was convened on September 8, 2020, to discuss and make recommendations related to classification of one unclassified, pre-amendments device type and reclassification of non-invasive bone growth stimulator devices. In Session I, the Panel was asked to discuss and make recommendations regarding the proposed classification of facet screw spinal device systems, which are currently unclassified, pre-amendment devices, to Class II (general and special controls). During session II, the Panel was asked to discuss and make recommendations regarding the reclassification of non-invasive bone growth stimulator devices, which are post-amendment devices, from Class III (general controls and premarket approval) to Class II (general and special controls).

Panel Discussion and Recommendations

Session I:

The Panel discussed the following FDA-identified risks to health for facet screw spinal device systems:

- Loosening/migration due to device failure or failure at the bone/implant interface
- Tissue injury
- Adverse tissue reactions
- Use error/Improper device use
- Pseudarthrosis due to device failure or failure at the bone/implant interface
- Adverse clinical sequelae

The Panel agreed with inclusion of the above FDA-identified risks in the overall risk assessment of the facet screw spinal device systems under product code "MRW". The Panel identified no additional risks, but recommended that certain risks be separately identified, such as neurological injury or device failure.
The Panel discussed the identified special controls and whether they appropriately mitigate the identified risks to health, or if additional or different special controls were necessary. The Panel discussions and feedback focused upon device biocompatibility, patient reported outcomes and neurological deficit. After Panel discussions and deliberations, the Panel agreed with the identified risks and mitigations as proposed and had no substantive additional recommendations regarding risks/mitigations.

After Panel discussions and deliberations, the Panel agreed with the FDA's proposed classification of Class II with special controls for facet screw spinal device systems.

Session II:

The Panel discussed the following FDA-identified risks to health for bone growth stimulator devices:

- Pain
- Failure or delay of osteogenesis
- Electromagnetic interference

- Adverse interaction with internal/external fixation devices
- Adverse biologic effects

The Panel discussed whether the list of risks proposed by FDA completely and accurately identifies the risks to health presented by non-invasive bone growth stimulator devices. The Panel suggested to better define the risk of adverse interaction with internal/external fixation device and either better define or delete the risk of adverse biological reaction. The Panel recommended that the signal characteristics need to be defined in a way to allow for a better characterization of the safety and effectiveness of the device.

The Panel discussed whether sufficient information exists to establish special controls for non-invasive bone growth stimulator devices. The Panel agreed with the FDA that the general controls are not sufficient to place these devices under Class I. The Panel generally agreed with the FDA that non-invasive bone growth stimulator devices are not life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health. With respect to preventing impairment of human health, some members of the Panel raised concerns about these devices potentially not treating an established non-union, and that this should be taken into consideration. The Panel also agreed with the FDA that non-invasive bone growth stimulator devices do not present a potential unreasonable risk of illness or injury, and sufficient information exists to develop special controls for these devices.

The Panel deliberated on whether the special controls listed by the FDA appropriately mitigate the identified risks to health of this device type, and whether additional or different special controls should be considered. The Panel generally agreed with the FDA's proposed special controls, including a special control requiring clinical data to demonstrate effectiveness, with the addition of a special control to require some level of postmarket surveillance. It was recommended that the clinical data special control specify a rigorous clinical study with at least one-year follow-up. With regards to interactions with other medical devices, the Panel recommended additional measures beyond device labeling. The Panel also recommended the need for quantifiable performance data.

After Panel discussions and deliberations, the Panel agreed with the FDA's proposed reclassification to Class II with special controls for non-invasive bone growth stimulator devices.

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