

**Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory  
Committee Meeting  
September 8-9, 2020  
FDA Virtual Meeting  
10903 New Hampshire Avenue  
Silver Spring, MD 20993**

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*As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the Orthopaedic and Rehabilitation Devices Advisory Panel for the purposes of obtaining recommendations about the classification and reclassification of orthopedic devices.*

*FDA is holding this panel meeting to obtain input on the risks and benefits of orthopedic devices for use. The Panel will be asked to recommend to FDA whether these devices should be up classified from Class I (subject only to General Controls) into Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.*

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**AGENDA – Orthopedic Devices (Day 1)**

8:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	Panel Chair
8:05 a.m.	Remarks from OHT6 Director	CAPT Raquel Peat, PhD, MPH
8:15 a.m.	Conflict of Interest Statement	Designated Federal Officer
8:20 a.m.	Open Public Hearing	
8:30 a.m.	Classification and Reclassification Overview	Constance Soves, PhD Brittany Ferrell
8:45 a.m.	FDA Presentation- Facet Screw System	Vikansha Dwivedi Caroline Moazzam, MD
9:15 a.m.	Panel Deliberations- Q & A	Panel Chair
9:50 a.m.	<i>BREAK</i>	
10:00 a.m.	FDA Presentations- Noninvasive Bone Growth Stimulator	Shumaya Ali, MPH Philip Belmont, MD Jesse Muir, PhD
10:40 a.m.	Q & A for FDA Presenters	
11:00 a.m.	<i>LUNCH</i>	
12:15 p.m.	Meeting Called Back to Order	Panel Chair
12:20 p.m.	Open Public Hearing	Panel Chair
1:20 p.m.	Panel Deliberations- Q & A	Panel Chair
2:25 p.m.	FDA Summation	CAPT Raquel Peat, PhD, MPH
2:35 p.m.	Proceedings Adjourned	LCDR Randoshia Miller, MS, BSN, RN

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**AGENDA – Orthopedic Devices (Day 2)**

8:00 a.m.	Call to Order, Opening Remarks & Introduction of the Committee	Panel Chair
8:05 a.m.	Remarks from OHT6 Director	CAPT Raquel Peat, PhD, MPH
8:10 a.m.	Conflict of Interest Statement	Designated Federal Officer
8:15 a.m.	Open Public Hearing	
8:20 a.m.	FDA Presentation- Semi-constrained toe joint prostheses	Michael Owens, MS Victoria Lilling, MD
8:40 a.m.	Panel Deliberations- Q & A	Panel Chair
9:25 a.m.	FDA Presentations- Intra-compartmental pressure monitor	Peter Allen, MS Neil Barkin, MD
10:00 a.m.	Panel Deliberations- Q & A	
10:30 a.m.	FDA Presentations-Intra-abdominal pressure monitoring devices	Cal Rabang, PhD Panel Chair
10:40 a.m.	Panel Deliberations- Q & A	
11:25 a.m.	FDA Summation	CAPT Raquel Peat, PhD, MPH
11:30 a.m.	Proceedings Adjourned	LCDR Randoshia Miller, MS, BSN, RN