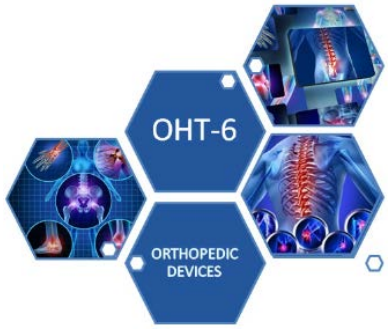
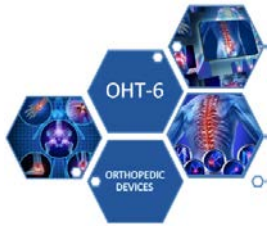


U.S. FOOD & DRUG ADMINISTRATION

Spinal Device Premarket Review Workshop

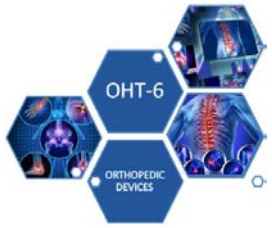
CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 13, 2020



Workshop Objective

To share information with all stakeholders; the public and regulatory affairs specialists to better understand how FDA reviews spinal devices 510(k) submissions by highlighting major sections of a 510(k) submission.



General Q & A Sessions

Please send your questions to:

OHT6-Feedback@fda.hhs.gov

Master of Ceremonies

Ms. Sharon Starowicz

Independent consultant and regulatory affairs specialist with over 30 years of experience (specializing in orthopedic and spinal devices).