



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0235]

Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Orthopaedic Sensing, Measuring, and Advanced Reporting Technology (SMART) Devices." The purpose of the public workshop is to discuss the development of Orthopaedic SMART Devices. The workshop is intended to enhance engagement with stakeholders to facilitate device development and to discuss scientific and regulatory challenges associated with Orthopaedic SMART Devices. Public input and feedback gained through this workshop may aid in the efficient development of innovative, safe, and effective Orthopaedic SMART Devices for better patient care.

DATES: The public workshop will be held on April 30, 2018, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by May 29, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer

to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 29, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of May 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0235 for "Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew Baumann, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 62, Rm. 2110, Silver Spring, MD 20993, 301-796-2508, andrew.baumann@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is sponsoring a public workshop to discuss the engineering, clinical, regulatory, cybersecurity, and real world evidence aspects of Orthopaedic SMART Devices. The

technologies of interest incorporate sensor equipped implants and instruments that generate information related to orthopaedic device performance and patient health. FDA understands that these technologies will play a role in the future of orthopaedics by providing objective data to the appropriate stakeholder that may optimize patient care. A public discussion of these topics will help the orthopaedic medical device community better understand the development of and considerations for these technologies. The workshop may help FDA and stakeholders prepare for the submittal and review of related applications.

II. Topics for Discussion at the Public Workshop

The public workshop will consist of presentations and panel discussions. Presentations will frame the topic and provide information on specific aspects of orthopaedic SMART device technology. Following the presentations, moderated discussions will ask speakers and additional panelists to provide their individual perspectives. Four rounds of presentations and panel discussions will cover the following topics:

- Engineering/Technology (morning)

This session will introduce orthopaedic sensor technologies and cover the current state of research and industry adoption. Future applications of these technologies will be explored.

- Clinical/Patient perspective (morning)

This session will cover the importance and potential utility of these technologies for clinicians and patients. Considerations for adopting these new technologies into existing health care paradigms will be discussed.

- Cybersecurity (afternoon)

This session will cover current cybersecurity issues and considerations. An overview of FDA's cybersecurity considerations and guidance documents will be presented.

- Regulatory Considerations (afternoon)

This session will discuss FDA's current and evolving thinking on Digital Health, clinical study considerations, including the role of real-world evidence, relevant guidance documents, and evidence generation related to Orthopaedic SMART Devices.

A detailed agenda will be posted on the following website in advance of the workshop: <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> and select this event from the list of items provided.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 20, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the

day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: Susan.Monahan@fda.hhs.gov, no later than April 16, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration Web page after April 20, 2018. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available approximately 45 days after the public workshop on the internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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