4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0303]

Robotically-Assisted Surgical Devices: Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the public workshop entitled "Robotically-Assisted Surgical (RAS) Devices: Challenges and Opportunities." FDA is holding this public workshop to obtain information on the current challenges and opportunities related to robotically-assisted surgical medical devices, which are classified as Class II medical devices. The purpose of this workshop is to obtain public feedback on scientific, clinical, and regulatory considerations associated with RAS devices. Comments and suggestions generated through this workshop will facilitate further development of regulatory science for RAS technologies.

Dates and Times: The public workshop will be held on July 27 and July 28, 2015, from 8 a.m. to 5 p.m.

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

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Mark Trumbore, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5402, Silver Spring, MD 20993, 301-796-5436, Mark.Trumbore@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by July 17, 2015, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting/public workshop will be provided beginning at 7 a.m.

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. 66, rm. 4321, Silver Spring, MD 20993-0002, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than July 14, 2015.

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 meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Mark Trumbore to register (see Contact Person). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by Friday, July 17, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after July 20, 2015. 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 http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to obtain information on the specific topics outlined in section II. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comment on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is August 26, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comment with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic(s) you are addressing. Received comments may be seen in the Division of Dockets Management between 9

a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts 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).

SUPPLEMENTARY INFORMATION:

I. Background

RAS devices, also known as computer-assisted surgical devices, are used by trained physicians in an operating room environment for laparoscopic surgical procedures in general surgery, cardiac, colorectal, gynecologic, head and neck, thoracic, and urologic surgical procedures. These medical devices enable the surgeon to use computer, software, and robotic technologies to control and move surgical instruments through the mouth or through one or more small incisions in the patient's body for a variety of surgical procedures. Some common procedures that may involve RAS devices include gallbladder, uterus, or prostate removal.

As discussed further in section II, there are several clinical and scientific challenges associated with regulation of RAS devices, such as appropriate nonclinical and clinical evaluation of RAS devices, use of third-party surgical instruments with legally marketed RAS

devices, and clinical training programs. This workshop seeks to involve industry and academia in addressing these challenges in the development of RAS devices to ensure that there is a reasonable assurance of safety and effectiveness for RAS devices while promoting innovation in a rapidly-developing field. By bringing together relevant stakeholders including scientists, patient advocates, clinicians, researchers, industry representatives, and regulators, we hope to facilitate the improvement of this evolving product area.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to, the following:

1. The current landscape of RAS devices and the respective Offices, Divisions, and Branches within FDA involved in the review of pre- and postmarket data associated with these devices.
2. Challenges, needs, and benefit/risk profiles for indications in various surgical areas; e.g. cardio/thoracic, gynecological, otolaryngological, urological, general.
3. Unique benefits of RAS devices versus traditional surgical procedures.
4. Scientific and technical considerations for third-party manufacturers seeking to claim that their surgical instruments can be used with legally marketed RAS devices.
5. Design, administration, and certification of training programs and FDA's role in this process.
6. The future landscape of RAS and robotic surgery devices.
7. Considerations regarding appropriate selection of preclinical (bench and animal) test methods and patient-centered outcome metrics in clinical use for different stages of device development.

These topics will be presented by experts in the associated area, followed by more in-depth discussions and Q&A from all participants.

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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