



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on April 16, 2020, from 8 a.m. to 6 p.m.

ADDRESSES: Doubletree by Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

The hotel's website is at: <https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.

5214, Silver Spring, MD 20993-0002, Aden.Asefa@fda.hhs.gov, 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On April 16, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics Organ Care System (OCS)--Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS--Heart, as stated in the PMA, is as follows:

The TransMedics Organ Care System (OCS) Heart System is a portable ex-vivo organ perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts with one or more of the following characteristics for transplantation into a potential recipient in a near-physiologic, normothermic, and beating state:

- Expected cross-clamp or ischemic time ≥ 4 hours due to donor or recipient characteristics (e.g., donor- recipient geographical distance, expected recipient surgical time)
- Donor age ≥ 55 years
- Donors with history cardiac arrest and downtime ≥ 20 minutes
- Donor history of alcohol use

- Donor LV ejection fraction (LVEF) $\leq 50\%$ but $\geq 40\%$
- Donor history of left ventricular hypertrophy (septal or posterior wall thickness of $>12 \leq 16$ mm).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 9, 2020. Oral presentations from the public will be scheduled on April 16, 2020, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 1, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 2, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Date: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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