

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

TDM

Display Date 10-14-08

Publication Date 10-15-08

Certifier A. Corbin

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 20, 2008, from 8 a.m. to 5:30 p.m.

Location: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4050, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625.

Please call the Information Line for up-to-date information on this meeting.

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 Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by Biosense Webster, Inc., a Johnson & Johnson Company, for the NaviStar ThermoCool irrigated RF ablation catheter. The device, an open-lumen, irrigated tip, steerable radiofrequency cardiac ablation catheter, is inserted through the venous circulation to the heart, across the intra-atrial septum to the left atrium to ablate cardiac tissue for the purposes of creating lines of block in the atria to eliminate conduction patterns that theoretically generate or allow propagation of paroxysmal atrial fibrillation.

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 Web site 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 Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee 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 October 30, 2008. Oral presentations from the public will be scheduled for approximately 30

minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Those desiring to make 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 October 22, 2008. 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 October 23, 2008.

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

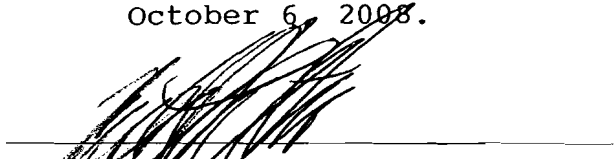
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240-276-8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.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).

Dated: 10/6/08

October 6, 2008.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**
