

# AGENDA

## CIRCULATORY SYSTEM DEVICES PANEL

**February 5, 2001**

Gaithersburg Marriott Washingtonian, 9751 Washingtonian Boulevard, Gaithersburg, Maryland

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| <b>8:00 a.m.</b>                                    | <b>Call to Order</b>   | <b>Cynthia Tracy, M.D., Chairperson</b> |
| <b>8:15 – 8:30 a.m.*</b>                            | <b>First Open Public Hearing*</b>                                      |   |
| <b>8:30 – 9:45 a.m.</b>                             | <b>Sponsor Presentation</b>  |   |
| <b>System</b>                                       | <b>Percusurge Guardwire Plus® Temporary Occlusion &amp; Aspiration</b> |   |
|   | <b>Percusurge-Medtronic K003992</b>                                    |   |
|   | Dennis Wahr, M.D., St. Joseph Mercy Hospital                           |   |
|   | Don Baim, M.D., Brigham & Women's Hospital                             |   |
|   | Rick Kuntz, M.D., HCRI-CDAC, Brigham & Women's Hospital                |   |
|   | Deborah Hinman, MSc, VP Regulatory Affairs, Percusurge-Medtronic       |   |
| <b>9:45 – 10:00 a.m.</b>                            | <b>FDA Presentation</b>  |   |
|   | Suzanne Kaiser, lead reviewer, FDA                                     |   |
|   | Paul Chandeysson, M.D., clinical reviewer, FDA                         |   |
| <b>10:00 a.m.</b>                                   | <b>Open Committee Discussion</b>                                       | <b>Cynthia Tracy, M.D.</b>              |
| <b>11:30 am</b>                                     | <b>Adjourn – Break for Lunch</b>                                       |   |
| <b>12:30 p.m.</b>                                   | <b>Call to Order: Open Discussion Session on</b>                       | <b>Cynthia Tracy, M.D.</b>              |
|   | <b>Clinical Study Design Issues for Distal Protection</b>              |   |
|   | <b>Devices used in SVG Disease</b>                                     |   |
| <b>12:30 – 2:00 p.m.**</b><br><b>(approx. time)</b> | <b>Second Open Public Hearing**</b>                                    |   |
| <b>2:00 p.m.</b>                                    | <b>FDA Presentation: Questions for the Panel</b>                       |   |
|   | Bram Zuckerman, M.D.   |   |
|   | Food and Drug Administration   |   |
| <b>2:15 p.m.</b>                                    | <b>Open Committee Discussion</b>                                       |   |
| <b>3:15 p.m.</b>                                    | <b>Adjourn</b>   |   |
| <b>3:15 – 3:30 p.m.</b>                             | <b>Break</b>   |   |
| <b>3:30 – 6:00 p.m.***</b>                          | <b>Closed Session***</b>   |   |

**FIRST OPEN PUBLIC HEARING\***

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. This Open Public Hearing will be kept short in order to allow sufficient time in the afternoon for scheduled speakers.

**SECOND OPEN PUBLIC HEARING\*\***

Before the afternoon discussion on Clinical Trial Issues, an open public session will be conducted for interested persons to address issues specific to the matter before the committee.

Ms. Moynahan will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Tracy will recognize unscheduled speakers as time allows.

The following people have requested time to speak:

- Richard Kuntz, M.D., Brigham & Women's Hospital
- Donald Baim, M.D., Brigham & Women's Hospital
- Dennis Wahr, M.D., St. Joseph Mercy Hospital
- Michael Gibson, M.D., UCSF Medical Center
- Deborah Hinman, MSc., Percusurge, Inc.
- Julie Broderick, Kensey Nash Corp.
- Gregg Stone, M.D., Lennox Hill Hospital
- Jim Gustafson, Possis Medical
- Jerry Mezger, CEO/President EndiCor Medical

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

**CLOSED SESSION\*\*\***

The session will be closed to the public from 3:30 – 6:00 p.m., in order to allow the Panel to hear trade secret and/or confidential information.