

ORTHOPEDIC AND REHABILITATION DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Gaithersburg Hilton
620 Perry Parkway
Gaithersburg, Maryland
August 31, 2004

Panel Chairperson

Michael J. Yaszemski, M.D., Ph.D.

Executive Secretary

Janet L. Scudiero, M.S.

8:00 am Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update since the June 2 and 3, 2004 Meeting
Barbara C. Zimmerman, Chief, Orthopedic Devices Branch

St. Francis Medical Technologies, Inc.
Intraspinous Process Distraction System, the X STOP® , P040001

8:15 am 1st Open Public Hearing*

8:45 am Sponsor Presentation

Yvonne Lysakowski, R.N., M.S., Vice President, Regulatory & Clinical Affairs
St. Francis Medical Technologies, Inc., Alameda, CA

Augustus A. White III, M.D., Ph.D., Orthopedic Surgeon-in Chief, Emeritus
Beth Israel Deaconess Medical Center and
Professor, Orthopedic Surgery, Harvard Medical School, Boston, MA

Scott Yerby, Ph.D., Director, Research & Development
St. Francis Medical Technologies, Inc., Alameda, CA

Gunnar Andersson, M.D., Ph.D., Senior Vice President, Medical Affairs
Professor, Department of Orthopedic Surgery
Rush University Medical Center, Chicago, IL

Charles Hartjen, M.D., Medical Director, The Spine Center at GBMC
Greater Baltimore Medical Center, Baltimore, MD

9:45 am FDA Presentation

John P. Holden, Ph.D., Biomedical Engineer
Barbara D. Buch, M.D., Medical Officer
Richard M. Kotz, M.S., Statistician

10:45 pm Break

11:00 pm Panel Deliberations and FDA Questions

12:00 am Lunch

- 1:00 pm Panel Deliberations, including FDA Questions**
John S. Kirkpatrick, M.D.
- 2:30 pm 2nd Open Public Hearing**
- 3:00 pm FDA and Sponsor Summations, up to 15 minutes each**
- 3:30 pm Panel Vote**
- 4:30 pm Adjournment**

?? **Open Public Hearings:** Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.