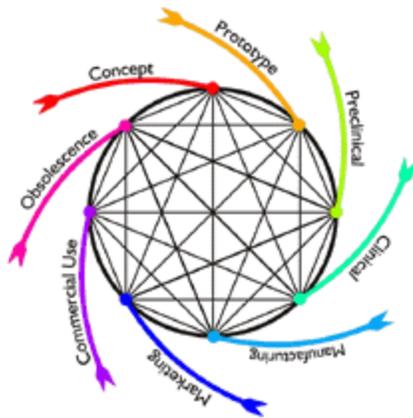




Center for Devices and Radiological Health
Office of Device Evaluation



*Ensuring the Health of the
Public Throughout the
Total Product Life Cycle --
It's Everybody's Business*



**DRAFT AGENDA
DENTAL PRODUCTS PANEL
Thursday, August 22, 2002**

4:00 – 4:15 p.m.

Closing comments
Dr. Leslie Heffez
Ms. Pamela D. Scott

4:15 p.m.

Meeting Adjourned

**DRAFT AGENDA
DENTAL PRODUCTS PANEL
Thursday, August 22, 2002**

ISSUE: REVIEW OF PREMARKET APPROVAL APPLICATION

SPONSOR: BIOMET, INCORPORATED

PRODUCT: Walter Lorenz Total Temporomandibular Joint Replacement System

BACKGROUND

The Walter Lorenz Total Temporomandibular Joint Replacement System is implanted in the jaw to functionally reconstruct a diseased and/or damaged temporomandibular joint. The Total TMJ Replacement System is a two component system comprised of mandibular condyle and glenoid fossa components. Both components are available in multiple sizes as right and left side specific designs and are attached to the bone by screws. The final device system as presented in this PMA submission includes two glenoid fossa designs, both available in small, medium, and large sizes. One design of the glenoid fossa has a post for cement use; the other design does not have a post. The mandibular component of the final system includes a narrow design, standard design, and an offset design (the offset design is also available in narrow and standard widths). The narrow and offset mandibular components are available in lengths ranging from 40 to 60 mm in 5 mm increments and the standard design is available in lengths of 45 mm, 50 mm, and 55 mm.

PANEL ACTIONS

The Panel is asked to provide a recommendation to the FDA on the above premarket approval application (PMA). The PMA must stand on its own merits and your recommendation must be supported by safety and effectiveness data in the application. Safety is defined as reasonable assurance, based on valid scientific evidence, that the probable benefits to health (under conditions of use) outweigh any probable risks [21CFR 860.7(d)(1)]. Effectiveness is defined as reasonable assurance that, in a significant portion of the population, the use of the device for its intended uses and conditions of use (when labeled) will provide clinically significant results [21 CFR 860.7(e)(1)]. The Panel's recommendation options for the vote are as follows: approval, approvable with conditions and not approvable.

**DRAFT AGENDA
DENTAL PRODUCTS PANEL
Thursday, August 22, 2002**

**DRAFT ROSTER
DENTAL PRODUCTS PANEL MEETING**

CHAIR

Dr. Leslie Heffez

Professor and Department Head of Oral and
Maxillofacial Surgery
University of Illinois, Chicago
Chicago, Illinois

EXECUTIVE SECRETARY

Ms. Pamela D. Scott

Biomedical Engineer, Dental Devices Branch
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices

VOTING PANEL MEMBERS	
<p>Dr. Kristi Anseth Patten Associate Professor Department of Chemical Engineering University of Colorado Boulder, Colorado</p>	<p>Dr. David Cochran Professor and Chairman Department of Periodontics University of Texas Health Science Center at San Antonio San Antonio, Texas</p>
<p>Dr. Edmond Hewlett Associate Professor Division of Cariology & Restorative Dentistry University of California at Los Angeles School of Dentistry Los Angeles, California</p>	<p>Dr. Diane Rekow Director of Translational Research and Professor of Orthodontics New York University College of Dentistry New York, New York</p>
<p>Dr. Jon Suzuki Professor School of Dental Medicine University of Pittsburgh Pittsburgh, Pennsylvania</p>	
CONSUMER REPRESENTATIVE	INDUSTRY REPRESENTATIVE
<p>Ms. Elizabeth Howe Outreach Coordinator National Foundation for Ectodermal Dysplasias Auburn, Washington</p>	<p>Mr. Daniel Schechter General Counsel Parkell, Inc. Farmingdale, New York</p>

**DRAFT AGENDA
DENTAL PRODUCTS PANEL
Thursday, August 22, 2002**

DRAFT ROSTER (CONTINUED)

PATIENT REPRESENTATIVE	
Ms. Elizabeth Helms President TMJ Society of California Sacramento, California	
PANEL CONSULTANTS	
Dr. Peter Bertrand Director, Orofacial Pain Clinic Specialty Advisor for Oral Facial Pain and TMD National Naval Medical Center Bethesda, Maryland	Dr. Richard Burton Assistant Professor of Oral and Maxillofacial Surgery Department of Hospital Dentistry University of Iowa Hospitals and Clinics Iowa City, Iowa
Dr. Janine Janosky Associate Professor Division of Biostatistics University of Pittsburg Dept. of Family Medicine and Clinical Epidemiology Pittsburgh, Pennsylvania 15261	Dr. Stephen Li President Medical Device Testing and Innovations
Dr. Mark R. Patters Chair Department of Periodontology College of Dentistry University of Tennessee Memphis, Tennessee	Dr. Jan Faulk-Eggleston Chief Oral and Maxillofacial Surgery Service Brooke Army Medical Center Fort Sam Houston, Texas

**DRAFT AGENDA
DENTAL PRODUCTS PANEL
Thursday, August 22, 2002**

FDA PARTICIPANTS	
<p>Dr. Susan Runner Branch Chief, Dental Devices Branch Division of Anesthesiology, General Hospital, Infection Control and Dental Devices ODE/CDRH/FDA</p>	<p>Dr. Kevin Mulry Dental Officer, Dental Devices Branch Division of Anesthesiology, General Hospital, Infection Control and Dental Devices ODE/CDRH/FDA</p>
<p>Ms. Angela Blackwell Biomedical Engineer, Dental Devices Branch Division of Anesthesiology, General Hospital, Infection Control and Dental Devices ODE/CDRH/FDA</p>	<p>Ms. Phyllis Silverman Biomedical Statistician Division of Biostatistics OSB/CDRH/FDA</p>

