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**SUMMARY MINUTES  
OF THE  
CIRCULATORY SYSTEM DEVICES PANEL MEETING**

**September 15-16, 1997**

**Gaithersburg Hilton  
Gaithersburg, Maryland**

## **ATTENDEES**

### **Acting Chairperson**

Anne B. Curtis, M.D.

### **Executive Secretary**

John E. Stuhlmuller, M.D.

### **Voting Members**

Francis R. Gilliam, III, M.D.

Tony W. Simmons, M.D.

### **Consultants Appointed to Temporary Voting Status**

Salim Aziz, M.D.

Michael D. Crittendon, M.D.

Michael J. Domanski, M.D.

Renee S. Hartz, M.D.

James R. Pluth, M.D.

David J. Skorton, M.D.

Cynthia N. Tracy, M.D.

George W. Vetovec, M.D.

Ronald W. Weintraub, M.D.

### **Industry Representative**

Mr. Gary Jarvis

### **Consumer Representative**

David A. Gooray

### **Food and Drug Administration Representatives**

Thomas J. Callahan, Ph.D.

Wolf Sapirstein, M.D., M.P.H.

Bette L. Lemperle, M.P.H.

Steven W. Allis, B.S.M.E.

Lisa M. Kennell, B.S.

Steven B. Kurtzman, M.D.

### **CALL TO ORDER AND OPENING REMARKS--September 15, 1997**

Acting Panel Chairperson Anne B. Curtis called the meeting to order at 9:35 a.m. and introduced Executive Secretary John E. Stuhlmuller, M.D., who read the conflict of interest statement. He noted that issues involving Drs. Curtis, Brinker, and Vetrovec had been considered but deemed unrelated to matters under discussion and that full waivers had been granted allowing their participation. He read nine appointments to temporary voting status and noted that Dr. Curtis had been appointed acting chairperson for the September 15-16, 1997 meeting.

There was no old or new business to discuss.

### **OPEN PUBLIC HEARING**

There were no scheduled speakers and no requests to address the panel.

### **OVERVIEW OF FDA PRODUCT DEVELOPMENT PROTOCOL**

Dorothy B. Abel gave an overview of a new FDA initiative called the Product Development Protocol (PDP), which is intended to be an alternative to the IDE/PMA process. This protocol would be a comprehensive document covering all phases from product development through marketing and would emphasize protocol and criteria rather than data. She noted that the PDP process has the advantages of being proactive, economical, and quicker in getting products to market, with no reduction in overall assurance of safety and effectiveness. Ms. Abel summarized the seven steps of the PDP process (presubmission, filing review, PDP submission/FDA review, including panel review, preclinical phase, clinical phase, notice of completion, and PDP completed) and the elements and timeframes for each, as well as the contents and methodology used in PDPs. She referred those wanting more information to the FDA

website at [www.fda.gov/cdrh/pdp/pdp.html](http://www.fda.gov/cdrh/pdp/pdp.html). In response to questions about panel input on study design, Ms. Abel noted that peer review groups such as professional societies would be included in early design phases and that comments from panel members on safety and effectiveness issues would remain important in the PDP process.

### **OPEN COMMITTEE DISCUSSION**

Dr. Curtis began the open committee discussion by asking Dr. Thomas J. Callahan of the FDA to make general comments about the criteria used in assessing heart valves in general. Dr. Callahan described results of a June 1993 National Institutes of Health workshop to devise an alternative plan for establishing objective criteria for evaluating heart valve devices. The three manufacturers presenting premarket approval applications at this panel meeting were the first three manufacturers to have followed those guidelines. He noted that approval decisions should be based on two factors: the Objective Performance Criteria (OPC) method and a risk-based decision based on freedom from thrombosis as well as sturdiness and effectiveness of the device. He emphasized the central issue of long-term follow-up, noting that panel recommendations may include postapproval studies.

### **PREMARKET APPROVAL APPLICATION 970002**

**Company Presentation.** Representatives of Alliance Medical Technologies introduced the PMA application for the Monostrut Heart Valve, a hingeless, free-floating, tilting disc device indicated for the replacement of malfunctioning native or prosthetic aortic or mitral heart valve. They reviewed the device's history from the

first clinical study at five international sites in 1982 to the present and described the device and its components. Preclinical testing results of in vitro and in vivo studies of hemodynamics and structural performance satisfied FDA guidance and showed acceptable hemodynamic and hematologic performance in dogs. The device also produced acceptable biocompatibility and toxicological testing results.

Sponsors presented clinical data on valve experience, noting that 569 aortic and 427 mitral valve replacements, based on a total of 1,113 patients, had produced no reports of structural failure and that the device had not been withdrawn from any of the 33 market countries. They gave an overview of the pivotal Canadian clinical trial, a nonrandomized objective trial based on three centers using comparison to historical controls (FDA-established OPC and literature-based). After summarizing inclusion and exclusion criteria and patient follow-up data, sponsors described its safety and efficacy performance as measured by OPC and New York Heart Association (NYHA) functional class assessments and concluded that the Monostrut heart valve is safe and effective in comparison with the OPC standard for replacement heart valves and that its hemodynamic and functional class data support safety and efficacy claims. They also concluded that the Monostrut is comparable to other FDA-approved valves based on FDA-selected literature and summaries of safety and effectiveness.

**FDA Presentation.** Team leader Lisa Kennell of the Division of Cardiovascular, Respiratory and Neurological Devices introduced the FDA review team members. She reviewed the history of the FDA Heart Valve Guidance Document and the history of the Monostrut PMA since its original submission in 1986, noting that the 1990 submission was recommended for nonapproval on April 12, 1993 with eight criteria given for correction of insufficient data. She discussed in detail the eight items that

were to be addressed to bring the PMA into approvable status, noting that five had been adequately addressed in the 1996 PMA revision. Dr. Kennell summarized the clinical data contained in the 1996 revision, noting that Cohort 1 consisted of three Canadian centers with isolate aortic valve sizes 21-27 mm and isolated mitral valve sizes 27-33 mm. and Cohort 2 consisted of two of the same three Canadian centers with valve sizes larger or smaller than the range of Cohort 1. These cohorts were combined as pivotal data for the meeting. Cohort 3, based on the original 1986 PMA dataset as supplemental data from a German center, was presented but not pivotal.

**Panel Reviewers.** Dr. George W. Vetrovec asked several questions on the data, specifically on the rigor and method used in patient follow-up. He also asked about guidelines for anticoagulation therapy, noting that the risk of thromboembolism seemed high. Sponsor representatives agreed that patients were generally under-anticoagulated by American standards, producing a low hemorrhage but a high thromboembolism rate. Dr. Vetrovec also asked about the variables affecting perivalvular leaks, specifically calcification in the annulus. Sponsors agreed that calcification in the annulus could predispose patients to perivalvular leaks but could not answer if such occurrences were more likely in older patients.

Dr. Ronald M. Weintraub began his review with concern about the small number of warnings, suggesting that some of the instructions for use should be moved to the warning section. Specifically he suggested a warning about using valve sizes provided by other manufacturers and about using the correct size, about not allowing the sutures to entrap the valve, and about using a holder to rotate the valve. He recommended a section on physician training and instructions about pushing the leaflet in to test the valve and suggested inclusion of a pusher device. He thought there was insufficient information about smaller sizes such as the 17 mm valve and

about long-term follow-up. He raised questions about the issue of confidence limits as related to company data and OPC data and noted that he found the hemodynamic evaluation data confusing but not essential to the PMA. He listed several safety issues: periprosthetic leaks, thromboembolism rates, and lack of information on the 19 mm valve and death rates.

**Panel Discussion.** Dr. Hartz and several of the panel members recommended that labeling information mandate prophylactic use of antibiotics for dental work and anticoagulation therapy. Use of an implant temporary identification card was also suggested until the permanent patient card arrives. Panel members were also concerned about insufficient data on the different valve sizes, particularly the 17 and 19 mm sizes, which some thought should be considered different valves. It was noted that the valve orientation should be specified in the labeling, with the aortic valve pointing toward the right lateral wall and the mitral pointing toward the left ventricular septum, and that the valve should be rotated in the annulus. Dr. Pluth also suggested a recommendation to downsize one valve size. Dr. Curtis suggested that the complication rates were acceptable but the follow-up data were not sufficiently rigorous.

In discussing the eight questions posed by the FDA, panel members agreed that the data presented permitted safety and effectiveness assessment. They felt that the indications and contraindications were sufficient, but recommended adding warnings about use of sizes provided by other manufacturers, about sutures not entrapping the valve, and about using a holder to rotate the valve and using the correct size. They agreed that the patient counseling information should be strengthened to mandate prophylactic antibiotic therapy and anticoagulation therapy after valve placement. They recommended a temporary wallet card upon discharge from the hospital and patient

instructions about the need to check INR and maintain anticoagulation therapy. Panel members suggested specifying the valve sizes for which there are data. They recommended physician training on valve insertion through a surgeon's manual and recommended post-marketing surveillance data on thromboembolism and perivalvular leak rates. They found the hemodynamic data inadequate or marginal and suggested postapproval studies to produce echocardiographic data.

After Dr. Stuhlmuller read the panel voting options, it was moved and seconded that the device be recommended for approval with the following conditions: (1) that the 17 and 19 mm aortic and 25 mm mitral valves be excluded; (2) that postmarketing studies be required on a cohort of mitral and aortic patients (number to be determined by FDA consultations), who would have postoperative and annual echocardiograms and a follow-up form, including thromboembolic conditions; (3) that there be a clinical and hemodynamic follow-up of study cohorts 1 and 2 for five years on perivalvular leaks, thromboembular events, Doppler echocardiography and NYHA functional class evaluation, including autopsy information on dead implant patients with case reports on explanted valves; and (4) that the warning section be strengthened about the mandatory need for anticoagulation and prophylactic antibiotic therapy. The motion was unanimously passed.

#### PREMARKET APPROVAL APPLICATION P970031

**Company Presentation.** Representatives from Medtronic Heart Valves, Inc. introduced the PMA application for the Medtronic Freestyle Aortic Root Bioprosthesis Model 995. The sponsor team described the device, noting that the aortic root design allows the physician to trim the prosthesis for replacement using the full-root, root-inclusion, or subcoronary technique. They gave an overview of the clinical study,

which was a prospective, nonrandomized, multicenter international clinical trial for isolated aortic valve replacement. Safety and effectiveness results were evaluated in terms of adverse events, NYHA classification, and hemodynamics. Data on patient demographics, distribution of valvular lesions, bioprosthesis size, ascending aorta pathologies, concomitant procedures and follow-up statistics were presented according to implant technique.

Sponsor representatives stated that safety results for all three techniques showed freedom from death as expected for patient pathology and age; no incidence of structural deterioration, nonstructural dysfunction, or primary hemolysis, and acceptable rates (two times the OPC rates) of adverse events for all implants and of all events for subcoronary implants. Complete echocardiographic studies evaluated hemodynamic performance, and echocardiographic data summaries included all patients.

In conclusion, sponsors stated that the Freestyle bioprosthesis demonstrated the versatility of an aortic homograft, acceptable freedom from death and adverse event rates, NYHA improvement after implantation, forward flow performance superior to stented bioprostheses; and minimal incidence of clinically significant regurgitation. They noted that education and training about the device would include classroom session, group interactive surgical observation sessions, technical materials, a wet lab, on-site observation session at a training surgeon's facility or an implant center, a valve registry, and post-training valve distribution.

**FDA Presentation.** FDA team leader Steven W. Allis introduced the members of the FDA review team and gave a description of the device, noting that it is a porcine aortic root available in five sizes and packaged in the full-root form. The implanting surgeon trims the aortic root tissue for replacement of the native valve, the aortic

root, or for modified root insertion within the native aorta using different implantation techniques. The subcoronary technique is used to replace the heart valve mechanism only. The root-inclusion style is for implantation within the native aorta after removal of the diseased valve. The full-root style is used to replace the entire native valve and aortic root.

Mr. Allis noted that the three styles studied in the Freestyle clinical trial are analyzed in separate cohorts, only one of which (the subcoronary) is composed of more than the FDA-recommended 800 patient-years of data. Three investigational centers have followed at least fifty subcoronary patients for more than one year, but no study centers have followed at least fifty root-inclusion or full-root patients for more than one year. The Freestyle subcoronary cohort also met the FDA criterion of at least 15 patients with one year of follow-up for each device size. For the root-inclusion cohort, the three largest sizes had more than 15 patients with one year of data, and for the full-root cohort, the two largest sizes had more than 15 patients at one year.

Mr. Allis noted that adverse event rates for the device were comparable for most events to the FDA OPC and several FDA-selected literature articles. The full-root technique showed higher linearized rates for mortality and a higher early mortality rate when compared to the other implant techniques. The Agency had no details regarding 31 implanted devices returned to the company for evaluation. Six subcoronary patients and four root-inclusion patients had Freestyle valves removed for subacute bacterial endocarditis and replaced with other types of prosthetic heart valves. Autopsy reports on three subcoronary, one root-inclusion, and five full-root replacements showed all devices macroscopically intact. The single root-inclusion valve showed minimal calcification upon histological examination. Morbidity was

comparable between cohorts and matched that in FDA-selected literature.

On effectiveness, the Freestyle device had improved pressure gradients and effective orifice areas compared to those reported for stented valves in FDA-selected literature. Valve regurgitation was noted in about a third of subcoronary patients, and one-tenth of patients receiving the two root styles. Valve leak in all cohorts was overwhelmingly mild.

Mr. Allis noted five limitations of the Freestyle clinical study, the first being that the criteria for use of different implantation styles were not established.

There was also limited experience with the root-inclusion and full-root styles. Third, the study had limited data for the smallest valve sizes in the root-inclusion and full-root styles. Data were also limited on calcification and durability beyond three years, with eight to ten years of follow-up data necessary on a heterograft to establish long-term durability. Finally, there was no information on explanted devices. Mr. Allis also asked for panel comments regarding the historical controls developed for observational studies, noting that this method relies on a side-by-side display of the Freestyle device and devices identified in the selected literature. He asked if this method should supplement or supplant the OPC.

**Panel Reviewers.** Dr. Salim Aziz began his review by commending both the FDA and Medtronic for a succinct, well-presented study. On the study design, he noted that a randomized study design using concurrent controls would be better than using historical controls. After summarizing safety and effectiveness criteria, patient selection, in vitro results, and clinical results, Dr. Aziz asked questions regarding the small number of younger patients, the percentage of patients having a concomitant root enlargement procedure, the use of antiplatelet agents in patients with stentless valves, the incidence of excessive operative bleeding in root replacement procedures,

and valve sizing for patients with small annulus but large body surface area.

Dr. Aziz also suggested that the company consider expanding surgeon training to increase comfort with the implantation technique for a stentless valve root replacement and institute some tracking system for following patients beyond three years to detect valve deterioration and valve-related events. He noted the difficulty of reoperations with the root replacement or inclusion techniques. He asked whether transcranial Doppler evaluations were done postoperatively and suggested such evaluation as compared to the embolic load seen with other valves.

In conclusion, Dr. Aziz noted that the stentless aortic valve has been reported to place less stress on the annulus than stented valves and that the valve is safe and effective as compared to historical controls in terms of preoperative and early mortality rates, perioperative and postoperative complications, thromboembolic-related events, adverse events, and in vitro testing. He suggested using the stentless valves in the Ross procedure to replace the removed pulmonary valve and in pediatrics for pulmonary valve replacement and possibly aortic valve replacement, but he saw no major advantage of using the stentless valve in patients with endocarditis versus using a homograft.

**Panel Discussion.** Dr. Domanski began the panel discussion by noting that age of the patient is a factor in the survival rates rather than the valve itself and that he thought the device was a good valve with an inadequate series of control data. He raised specific questions relating to death, reoperation, and explant data and reiterated that he had problems with both the control factors and the selection of articles from literature, saying that the populations were really not comparable.

Other panel members were concerned about issues of durability and calcification, particularly with younger patient populations. Several suggested the need for longer-

term follow-up in these areas, as well as more studies on explanted devices. Other panel concerns related to surgeon training and whether it should be mandatory; sponsors discussed the training program components in more detail. Dr. Hartz suggested that safety of the implant technique be discussed in the labeling and that patient counseling should include stronger warnings on the mandatory use of prophylactic antibiotics and the use of a temporary wallet card. She also suggested more work on the physician training section, including a note that the implantation takes longer; instructions on suturing technique; mention of the need for anticoagulation therapy; and a diagram on prosthesis placement. Dr. Curtis suggested that the indications for use should be similar to other tissue valves and not be restricted by age other than a general recommendation suggesting its use in those over 65, with life expectancy data given.

In discussing the FDA questions, the panel agreed that there was enough information to assess safety and effectiveness. Members agreed to put data in the labeling so that the physician can make a personal judgment on device durability. They suggested no contraindications beyond the normal good judgment required with the use of bioprostheses and a note that generically tissue valves tend to deteriorate in younger patients. Patient counseling information should mandate the use of prophylactic antibiotics and anticoagulation therapy and the use of a temporary wallet card. They suggested postmarketing studies on the full-root technique and notation of the paucity of data on the 19 and 21 mm size roots. They recommended mandatory physician training, with the company providing a course of instruction; a wet lab; and observation of live operations, especially the full-root procedure.

On methodology, the panel recommended the use of randomized clinical trials and suggested that it is better to use a database or source than to take articles from

the literature. They suggested selecting OPC data for the database for the next group of valves.

After Dr. Stuhlmuller read the voting options, a motion was made and seconded to approve the PMA application with the following conditions: (1) that postmarketing studies be conducted to provide follow-up data on all valve sizes and implantation methods, using annual echocardiographic analysis and clinical evaluation of the cohort, including notation of the use of anticoagulation medication, incidence of thromboembolism, NYHA functional classification, and correlation of age and freedom from reoperation; (2) that a required surgeons' training program be established in consultation with the FDA staff; (3) that labeling be added to include the insufficiency of data in the smaller sizes, the mandatory use of prophylactic antibiotic therapy, and the use of a temporary wallet card and (4) that a core pathology lab examine any explanted valves. The motion was unanimously approved.

The meeting was adjourned at 6:30 p.m.

## **CALL TO ORDER AND OPENING REMARKS--SEPTEMBER 16, 1997**

Acting Chairperson Anne B. Curtis, M.D., called the meeting to order at 8:35 a.m. Executive Secretary John E. Stuhlmuller, M.D., read the conflict of interest statement and noted that matters relating to Drs. Curtis, Brinker, and Vetrovec had been considered but deemed to pose no conflict of interest and full waivers had been granted for their participation. He read appointments to temporary voting status for nine consultants and an appointment to acting chairperson for Dr. Curtis for the September 15-16, 1997 meeting.

There was no old or new business.

## **OPEN PUBLIC HEARING**

Dr. Gordon R. Bernard had requested time to update the panel on the Pulmonary Artery Catheterization and Clinical Outcomes Conference (PACCO), held on August 24-25, 1997. He outlined the pulmonary artery catheter (PAC) problem by saying that one million catheters are inserted per year for both diagnosis and management by a wide variety of operators, but no reports document decreased mortality and several reports associate PAC use with increased mortality. He listed studies on whether the PAC increases mortality in cardiac surgery, in acute myocardial infarction, and in mixed intensive care units and cited a Journal of American Medical Association article on the effectiveness of right heart catheterization. He observed that the risk of death compared to matched controls was increased, with the highest risk for acute respiratory failure and multiple organ failure. The risk was similar to controls for congestive heart failure, and no group had improved outcome with PAC.

Dr. Bernard listed the professional and government organizations in PACCO,

discussed its purpose, and outlined its committee organization. PACCO recommendations are that professional societies create mechanisms for improved PAC training, credentialing, and monitoring; that prospective randomized trials assess safety and efficacy in persistent refractory heart failure, acute respiratory distress syndrome, severe sepsis/septic shock, and low-risk CABG surgery patients using carefully designed control groups; and that the PAC model be developed and extended to improve methods for evaluation and employment of medical devices in intensive care.

Panel member Dr. Michael Domanski made a suggestion on the previous day's discussion that while it would be useful to create historical controls on heart valves, another approach would be to use truly randomized studies, accepting that the power is low but looking for truly gross differences in data.

There were no other requests to address the panel.

#### PREMARKET APPROVAL APPLICATION P970030

**Company Presentation.** Representatives from St. Jude Medical began the presentation on the Toronto SPV Valve, a stentless, subcoronary, intact porcine valve with scalloped sinuses for subcoronary implant without modification. After listing the participating clinical investigators, sponsors compared the SPV valve to a stented valve, described its design and rationale behind the design, and discussed the surgical implantation technique.

Sponsors also presented results of a multicenter, prospective, observational clinical trial based on 12 sites in North America and England with the objective of demonstrating that the rate of serious complications does not exceed twice the OPC rate. Statistics were given on aortic valve disease etiology, valve sizes implanted,

concomitant procedures, and NYHA classification by visit. Safety and efficacy data on complication rates and causes of death were analyzed, with the conclusion that 98% of implanted patients were NYHA functional class I or II throughout follow-up; that rates for all serious adverse events were less than twice the OPC, and that no unanticipated adverse events were reported.

Sponsor representatives presented data on hemodynamic performance, including mean gradient at one year, peak gradient at one year, EOA at one year, severity of aortic insufficiency, and left ventricular mass over time. Hemodynamic findings through echocardiography showed thin, mobile leaflets, low transvalvular gradients, large and effective orifice area, low incidence of significant regurgitation, and left ventricular mass regression. Sponsors concluded that the valve provides a consistent subcoronary design, a reproducible implant technique, near-natural hemodynamics, and safety and efficacy in all valve sizes.

Sponsors also described physician training through a global education program established at the St. Jude Medical Institute. Training consists of a lecture on the history of the valve, teleconferencing and videoconferencing to allow operation viewing, and a wet lab experience. A physician's manual will also include a discussion of valve sizing and implantation technique. Sponsors had a draft proposal for postmarketing studies that would include long-term safety and efficacy studies following the North American cohort to the year 2002 for information on adverse events, NYHA classification, echocardiography results, mortality rate, and autopsy information. Such studies would detect rare adverse events, determine predictors of valve failure, and provide annual adverse event reports to the FDA.

**FDA Presentation.** Lead reviewer Steven Allis introduced the FDA review team for the Toronto SPV valve, describing its design, fixation, and available sizing. He

described statistics from the SPV valve study in comparison to the FDA Heart Valve Guidance and discussed early as well as late mortality and morbidity rates. Effectiveness of hemodynamic performance was assessed in terms of pressure gradients, effective orifice area, and valve regurgitation, which were comparable to homografts. Mr. Allis noted the limitations of the clinical study in data for smaller sizes, in data beyond four years on calcification and durability, and in study of explanted valves.

**Panel Reviewer.** Dr. Michael D. Crittendon began the panel review by complimenting the sponsor on the clinical summary. He touched briefly on points relating to hemodynamics figures, particularly the rate of left ventricular mass regression as compared to core lab data; to calcification and whether there was evidence of it in the six explants, to confusing figures on aortic regurgitation, and to technical aspects of whether the valve was easier to implant than homografts. He recommended a rewording of the section on surgical technique in the St. Jude physician manual, which he thought confusing.

Panel questions concerned the lack of data on smaller valve size; it was noted that the smaller sizes were included because the design and technique were identical; the hemodynamic performance was good in all models; there were no statistically significant differences across valve sizes; and a patient group could benefit from inclusion of smaller sizes. Panel members suggested the need for continued studies to produce more data, although the valve performed well across all sizes. It was noted that explantation is difficult but can be done. Concerns were raised about the effects of calcification, particularly in pediatric patients, but there was disagreement about the effectiveness of extrapolating from animal studies. Panel members suggested using randomized prospective trials and using control articles secondarily as a review guide

but not deriving P values from them.

It was noted that the valve should not be used with active endocarditis; the endocarditis should be cleared first before valve implantation. It was also noted that anticoagulation therapy should be based on the individual patient's condition and on the physician's recommendation and that data on anticoagulation therapy results should be shown rather than specifying a particular recommendation. There was panel concern about overall safety of all valves, with panel members noting that ten-year results are not yet in. It was recommended that warnings be added about use of prophylactic antibiotics for dental work and a temporary warning card be included. Physician instructions should include the use of a fixation suture rather than a hemostatic, and use of a smaller needle.

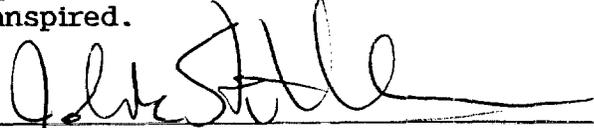
In answer to the FDA questions, panel members agreed that the data was sufficient for assessment. They suggested adding a warning that active endocarditis is a contraindication for using this valve, strengthening the patient counseling information to mandate prophylactic antibiotic therapy for potentially bacteremic procedures, and adding a temporary wallet card. Panel members suggested changing the labeling to show surgeons that there are limited or no data available on the smaller size valves and no data for periods longer than four years.

It was moved and seconded that the application be recommended for approval subject to the following conditions: (1) that the FDA and the sponsor agree on echocardiographic standards for the way future data are obtained; (2) that the labeling be amended to indicate the lack of data on smaller valve size and to include mandatory use of prophylactic antibiotic therapy during bacteremic procedures and the use of a temporary wallet card; (3) that a warning be added contraindicating use with active endocarditis; (4) that the PMA include detailed postapproval surveillance

as the presenters described in their draft proposal, particularly with reference to the smaller size valves; and (5) that physician training be mandated as described by the presenters and that a paragraph in the physician packet make the anatomical and technical descriptions more standard. The motion passed unanimously.

The meeting was adjourned at 11:40 a.m.

I certify that I attended the Circulatory Devices Panel Meeting on September 15-16, 1997, and that this summary accurately reflects what transpired.

  
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John Stuhlmuller  
Executive Secretary

17 Nov 97 mg

I approve the minutes of this meeting as recorded.

  
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Anne B. Curtis, M.D.  
Acting Chairperson

Summary minutes prepared by Aileen M. Moodie  
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