SUMMARY MINUTES

OF THE

OPHTHALMIC DEVICES PANEL MEETING

NINETY-SIXTH MEETING

SEPTEMBER 23, 1999

OPEN SESSION

Silver Spring Holiday Inn
Silver Spring, Maryland

OPHTHALMIC DEVICES PANEL MEETING

September 23, 1999

PANEL PARTICIPANTS

James P. McCulley, M.D.	Chair
Mark A. Bullimore, MCOptom, Ph.D.	Voting Member
Eve J. Higginbotham, M.D.	Voting Member
Janice M. Jurkus, O.D.	Voting Member
Jose S. Pulido, M.D.	Voting Member
Joel Sugar, M.D.	Voting Member
Scott M. MacRae, M.D.	Consultant
Leo J. Maguire, M.D.	Consultant
Dan Z. Reinstein, M.D., M.A., FRCS	Guest Discussant
Marcia S. Yaross, Ph.D.	Industry Representative

FOOD AND DRUG ADMINISTRATION PARTICIPANTS

Sara M. Thornton	Panel Executive Secretary
Donna R Lochner	Chief Intraocular and Corneal Implants Branch
Everette T. Beers, Ph.D.	Acting Chief Diagnostic and Surgical Devices Branch
Quynh T.N.Hoang	Electrical Engineer Diagnostic and Surgical Devices Branch
Joel Glover	Biomedical Engineer Intraocular and Corneal Implants Branch

PARTICIPANTS IN THE OPEN GROUP DISCUSSION

NAME	REPRESENTING
Judy F. Gordon, D.V.M.	ClinReg Consulting Services, Inc.
R. Doyle Stulting, M.D., Ph.D.	American Academy of Ophthalmology
Michael T. Bartell	Microtech, Inc.
Charles A. Mastellone	Microtech, Inc.
Douglas E. Mastel	Mastel Precision
Curt L. Taylor	Mastel Precision
Alex Sacharoff, Ph.D.	Summit Technology
George Myers	Hawken Industries
Shirley McGarvey	Autonomous Technology

OPEN SESSION-SEPTEMBER 23, 1999

CALL TO ORDER

Dr. James P. McCulley, Panel Chair, called the meeting to order at 8:45 a.m. **Ms. Sara M. Thornton, Executive Secretary,** announced that the tentatively scheduled November 18- 19, 1999, meeting date had been canceled and that meeting dates for the year 2000 included January 13-14, March16-17, May 11-12, July 27-28, September 21-22, and November 8-9. She introduced new panel member Dr. Leo Maguire and guest discussant Dr. Dan Reinstein and asked the other panel members to introduce themselves.

FDA PRESENTATION

Larry G. Kessler, director of the FDA Office of Surveillance and Biometrics, gave the panel a presentation on postmarket surveillance and methods of postmarket evaluation at CDRH. He explained that medical devices have a definable life cycle, in which the clinical community has an important role to play in providing feedback during postmarket evaluation. He outlined the questions assessed in the postmarket period and described the Medical Device Reporting (MDR) Program, which provides limited but critical information to FDA about devices with problems, and he listed the possible actions prompted by such a medical device report. Mr. Kessler discussed the two postmarket authorities, postmarketing surveillance and postapproval authority, and outlined the criteria for a panel to suggest postmarketing surveillance as well as study designs used in postmarketing surveillance. He acknowledged the frustrations involved in monitoring the postmarketing period and challenged the advisory panel to ensure that a postmarketing study will be

of primary importance, to specify the public health question it is to address, and to note what will be done with the data collected. He briefly outlined the future of the MDR and Postmarketing Surveillance programs.

Dr. McCulley noted the tendency of some FDA panels to request postmarketing studies as a way of dealing with "gray areas" involving incomplete or insufficient data. Mr. Kessler stated that FDA has an ongoing review of postmarketing studies to see if they addressed the questions panels had asked them to clarify. Again, he urged the panel to use postmarket evaluation to get relevant public health data but stressed the need for the panel to identify their primary concerns and the uses to which such data would be put.

Ms. Donna Lochner, Chief of the Intraocular and Cornea1 Implants Branch, gave the branch update. She reported on the postmarketing surveillance study requested by the panel as a condition of approval for the Staar Surgical Company's toric posterior chamber intraocular lens (IOL), Model AA4203TF and Model AS42203T, for patients with preexisting cornea1 cylinder. The study, which involved the first 1,000 implants following PMA approval, showed a reported significant repositioning rate of 6.6% of the IOL, with no reports of adverse events or lens dislocations associated with the repositionings. Ms. Lochner stated that the sponsor had modified their product labeling to include this information.

Dr. Everette T. Beers, Acting Chief of the Diagnostic and Surgical Devices Branch, stated that the following PMAs are still under review: P970001 - EmoryVision Correction Center's refractive surgery laser for myopia using LASIK; P990010 - CRS, Inc.'s PMA using the VISX laser

to correct myopia using LASIK; P930034/S13 for Summit Technology's PMA supplement with CRS data for laser correction of myopia using LASIK; and P980051 for Sunrise Technology's holmium laser for laser thermal keratoplasty correction of hyperopia.

Executive Secretary Sara Thornton read the conflict of interest statement, noting that waivers had been granted to Drs. MacRae and Higginbotham and that matters concerning Drs. Higginbotham, MacRae, Bullimore, and Jurkus had been considered but their full participation allowed.

Dr. A. Ralph Rosenthal, director of the Division of Ophthalmic Devices, gave introductory remarks for the keratome discussion. He stated that the stakeholders in this discussion had been invited to help develop a guidance document addressing safety and effectiveness issues for all indications for use of keratomes, including making corneal flaps for LASIK. Dr. Rosenthal noted that the first PMA for an individual laser for LASIK had recently been approved, and several PMAs had been presented for commercially produced lasers seeking the LASIK indication. Keratome manufacturers have also submitted 510(k) applications to FDA to revise their labeling to include LASIK, but no such application had as yet been cleared. He asked the panel to provide input on the additional information, if any, needed to determine safety and effectiveness of keratomes for use in LASIK and to discuss the risks associated with the keratome when used in that procedure.

OPEN PUBLIC HEARING

Mr. Michael T. Bartell, president of Microtech, Inc., stressed the importance of having the FDA protect the integrity of the microkeratomes that prove themselves worthy of FDA approval.

He requested that the current FDA policy for generic component products for microkeratome systems be changed and that the substitution of generic components to an approved microkeratome system be reviewed by the FDA as an off-label use of that system. Mr. Bar-tell further stated that if the FDA continues to grant 5 1 O(k) market clearance to manufacturers of generic components, it is jeopardizing patient safety and product reliability and should be willing to assume the product liability of the whole system.

Dr. McCulley noted that the panel heard and understood the message but does not regulate blades. Dr. Rosenthal stated that the issue could be addressed when the final guidance is written.

Douglas E. Mastel, president of Mastel Precision, raised issues relating to the metallurgical physical properties of stainless steel microkeratome blades. He discussed facets of edge sharpness, using x-ray diffraction for elemental and microstructure analysis to find the best material, and infrared spectroscopy to examine samples of new and used blades.

George H. Myers, a consultant to Hawken Industries, listed six questions to be considered involving the use of microkeratomes for LASIK, including stroma smoothness, edge definition, flap thickness, effects of cornea1 curvature and geometry, intraocular pressure, and long-term effects of superior hinges. He suggested that data be supplied with 5 10(k)s concerning these questions and that a registry be kept on the effect of these parameters. He suggested the following items for 5 10(k) inclusion: animal tests to establish flap thickness, human tests to substantiate animal results, and scanning electron microscopy of the stromal beds and edges on animals, He also listed general suggestions involving maximum pressure used to hold the device, test results and

specifications on belts and moving parts, indications. of speed constancy and accuracy of cut for various devices, and asked about cleared devices not commonly used by the profession.

OPEN PUBLIC DISCUSSION

Session l-Problems Associated with Keratomes

The panel and open group discussants considered a draft list presented by FDA staff members Quynh Hoang and Joel Glover of the clinical problems associated with keratomes. No items were removed from the list, but a number were added. The final list is given below.

Session 2-Probable Causes

The panel and open group discussants identified the probable causes for each problem and divided those causes into device-related, operator-related, and patient-related causes. The final list is given below.

Session 3-Steps to Mitigate the Problems

The panel and participants listed how each of the problems could be mitigated through device design, labeling, user training, or similar actions. The final list is given below.

Important	Epithelial in-growth	Clean cut/ Appropriate bevel/no epithelial defects	Appropriate flap alignment; removal of interface fluid; seating; keep epithelium lubricated; management of epith. defects; inspection	Aware those with anterior membrane dystrophy; dry eye; flap dislocation (rubbing); patient compliance; previous surgery	As above plus Patient educatio
Important	Flap dislocated, slippage realignment, wrinkles, microfolds, cracks, irregular astigmatism	Creation of a stable flap as related to bevel, thickness, diameter, hinge placement in relation to ablation bed; track-in-rail vs. pivotal	Surgeon assurance of a stable flap; confirmation of flap adhesion	Same as above	As above plus Operator Education
Important	infection	Sterility assurance and maintenance; keeping device from contacting non-sterile surfaces (lid)	Maintain sterility; patient selection	Patient compliance	As discussed in Causes Device design allows for easy cleaning an sterilization
Less critical issue	Interrupted movement;partial flap	Device not stopped because of minor obstruction;excessive wear; inadequate torque; electrical failures; adequate education of users	Inadequate maintenance; regular verification of function	Patient cooperation; patient anatomy	As discussed In Causes

Important	Lamellar keratitis (focal, diffuse)	Device doesn't leak; not susceptible to contaminants (incl. blade, solutions)	Equipment maintenance; operator maintenance of an isolated sterile field (lid isolation)	Individual patient contributing risk factors	Device allows : easy cleaning and sterilizatio
Very Important	Suction (IO); consistency of, loss of, maintenance of;	Decrease in suction as discussed			Tonometry;
	Ocular ischemia;	Inadequate buildup and release time; excessive IOP generated (typically 60-80 mmHG)	Inability to use device efficiently in a short time (bail out time at ~2.5-3min)	Individual susceptibility to ischemic damage and poor cooperation	Limits on amount of pres and length of duration; alarms
	Decentration of flap	Slow suction	Appropriate centration of suction ring	Cooperation and anatomy (conjunctival, scleral, curvature)	Adequate rate suction

Not as important	Interface debris: metal shavings, etc.	Blade quality control; seal of motor; appropriate maintenance blade reuse	Maintenance of an isolated sterile field; cleaning and sterilization For blade reuse; avoid introducing particulate matter (glove w/talc)		As discussed previously
Important	Epithelial defects (central vs. peripheral)	Blade quality; reuse of blade; surface quality of foot plate (maintainability); blade/plate association (folding of flap): blade/plate gap; design where plate trauma is excessive; blade depth	Maintenance of device; maintain health of epithelium; with manual operation, same forward and reverse speed	Avoid those w/ anterior membrane dystrophy; underlying systemic disease making the epithelium vulnerable; previous contact lens wearer	As discussed previously
Less important for considera-tion	bleeding		Decentration; incorrect flap size	Individual characteristics (small eye)	As discussed previously

The panel recommended that standardized labeling information and standardized measurement technique be used in live eyes.

OPEN COMMITTEE DISCUSSION

The panel then ranked the above list by seriousness or importance.

The Industry Representative to the panel suggested that the panel think in the future about how one would use clinical data since the keratomes are often used in conjunction with other devices.

There were no additional requests to make public comments. Dr. Rosenthal and Dr. McCulley thanked the public presenters and the panel members. Ms. Thornton noted that the above chart would be probably be available on the FDA website, noting that the day's discussion was a new trial format for FDA panels. She thanked Dr. McCulley and the panel members. Dr. McCulley adjourned the session at 4:45 p.m.

certify that I attended the Open Session of the Ophthalmic Devices Advisory Panel Meeting on September 23, 1999, and that this summary accurately reflects what transpired.

Sara M. Thornton
Executive Secretary

I approve the minutes of this meeting as recorded in this summary.

James P. McCulley, M.D.
Chair

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