K132549

APR 2 3 2014

ACCUTOME

510(k) SUMMARY: AccuTip Cover

Applicant:	Accutome, Inc.
Address:	3222 Phoenixville Pike Malvern, PA 19355
Contact Person:	Adam Pickholtz Manager QA/QC
Telephone:	(610) 889-0200 (610) 889-3233 Fax
Preparation Date:	July 30, 2013
Trade Name:	AccuTip Cover
Common Name:	Tonometer tip cover
Classification Name:	Tonometer and accessories (21 CFR 886.1930, Product Code: HKY)
Legally Marketed Predicate Devices:	Ocu-Lab Ocu-Film Tip Cover (K882750)
Description of the Device:	The AccuTip Cover is a non-sterile, sanitized, single use latex disposable. It is used to cover the tip of a handheld tonometer.
Indications for Use:	An AccuTip Cover is applied over the tip of a handheld tonometer prior to performing tonometry. The tip cover is used for protection of the patient's eye and the instrument tip.

Intended Use:

The AccuTip Cover is intended to be used in conjunction with a handheld tonometer by trained individuals experienced in taking intraocular pressure measurements.

Comparison of Technological Characteristics to the predicate device:

Both the AccuTip Cover and the Ocu-FilmTip Cover are shaped to cover the tip of a handheld tonometer, and are used to protect patients from cross contamination and to protect the tonometer sensors from dust or fluids. The two finished products have been tested to the same biocompatibility standards and are both made of natural rubber latex. Both the AccuTip Cover and the Ocu-Film Tip Cover are sanitized through the use of gamma irradiation.

Standards Testing:

EN/ISO 10993 - Biological Evaluation of Medical Devices
Compliance per Toxicon reports 13-01358-G1, 13-01358-G2, and 13-01358-G3.

FDA G95-1, Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995

Verification Testing:

Internal design verification testing was conducted on the AccuTip cover for verification that the product met all the proposed design inputs and outputs.

Results: The AccuTip cover design met all of the proposed design inputs and outputs.

Comparison Test:

A comparison test was conducted to compare tonometer readings taken with an AccuTip cover and readings taken with the predicate device.

Results:

Readings with the AccuTip cover as compared to readings with the predicate were within the proposed acceptance criteria.

Validation Testing:

An internal validation plan was developed and tested for the AccuTip Cover to assure that the product meets the specified intended use and method of application.

Results:

All features were fully functional and met the specified intended use and method of application.

High Level Disinfection Validation:

A determination of bioburden was conducted on AccuTip cover samples. Samples were then validated to the appropriate sterility assurance level and results were documented.

Results:

The samples met the pre-determined acceptance criteria.

Aging Testing:

AccuTip Cover samples were irradiated via a validated method and incubated for a 1 year accelerated aging study. The samples were then tested for integrity and other possible defects.

Results:

The aged samples met the pre-determined acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 23, 2014

Accutome, Inc.
Mr. Adam Pickholtz
Manager QA/QC
3222 Phoenixville Pike
Malvern, PA 19355

Re: K132549
Trade Name: AccuTip Cover
Regulation Number: 21 CFR 886.1930
Regulation Name: Manual tonometer & accessories
Regulatory Class: Class II
Product Code: HKY
Dated: April 7, 2014
Received: April 10, 2014

Dear Mr. Pickholtz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name:

AccuTip Cover

Indications for Use:

An AccuTip Cover is applied over the tip of a handheld tonometer prior to performing tonometry. The tip cover is used for protection of the patient's eye and the instrument tip.

Prescription Use___X___ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K132549