K971439

JUN 17 1997

Storz Instrument Company
Storz MicroFlow Plus, Storz MicroFlow Plus Angled, and Storz Standard Angled Phacoemulsification Needles
510(k) Summary of Safety and Effectiveness

The following information is submitted in accordance with the requirements of 21 CFR § 807.92:

Submitted by:

Michael H. Southworth RAC
Group Manager, Regulatory Affairs
Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

Contact Person: Patrick G. Balsmann, 314-225-5051, ext. 5538

Date Prepared: 16 April 1997

Proprietary Name: Storz MicroFlow Plus, Storz MicroFlow Plus Angled, and Storz Standard Angled Phacoemulsification Needles

Common/Usual Name: Phacoemulsification Needles

Classification Name: System, Phacofragmentation, 86(HQC). Phacoemulsification needles are accessories to "Phacofragmentation Systems" which are Class II medical devices in accordance with 21 CFR § 886.4670.

Intended Use: The new Storz MicroFlow Plus, MicroFlow Plus Angled, and Standard Angled Phacoemulsification Needles are accessories to a phacoemulsification handpiece, which is intended for use in the ultrasonic surgical removal of the cataractous crystalline lens.

Device Description: A phaco needle is the cylindrical, metal tip which is connected to the distal end of a phaco handpiece. The needle is the component of a phaco system which, as driven by the ultrasonic handpiece, contacts and fragments the crystalline lens. Irrigation fluid flows between the external surface of the needle and the internal surface of an irrigation sleeve and into the eye. The emulsified lens material and irrigant are aspirated from the eye through the lumen of the phaco needle.

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Predicate Devices: The Storz MicroFlow Plus, Storz MicroFlow Plus Angled, and Storz Standard Angled Phacoemulsification Needles are substantially equivalent to legally marketed predicate devices. The Storz MicroFlow Plus and Storz MicroFlow Plus Angled Phaco Needles are subsatantially equivalent to the existing Storz MicroFlow Phaco Needles (K954340), the Storz MicroSeal Phaco Needles (K952259), and the Surgin High-Performance Phaco Tips (K943102). The Storz Standard Angled Phaco Needles are substnatially equivalent to the existing Storz Standard Phaco Needles (K946176) and the Surgin High-Performance Phaco Tips (K943102). Charts comparing basic characteristics of these new Storz Phaco Needles to those of the predicate devices, demonstrating substantial equivalence, are attached.

Substantial Equivalence Chart
Storz MicroFlow Plus and MicroFlow Plus Angled Phaco Needles

Device Characteristic	Storz MicroFlow Plus	Storz MicroFlow Plus, Angled	Storz MicroFlow	Storz MicroSeal	Surgin High-Efficiency
510(k)	present	present	K954340	K952259	K943102
Intended Use	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.
Number of Models	Four	Four	Four	Two	Two
Model Variations	Needle tip bevel angle	Needle tip bevel angle	Needle tip bevel angle	Needle tip bevel angle	Degree angled shaft
Angled Shaft	No	Yes	No	No	Yes
Material(s)	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Titanium (alloy unknown)
Needle I.D. (inches)	0.024	0.024	0.020	0.024	0.026
Needle O.D. (inches)	0.046	0.046	0.046	0.042	0.036
Recommended Surgical Incision Size (mm)	2.8	2.8	2.5	2.5	2.75
Number of Uses Recommended	10	10	10	5	Unknown

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Substantial Equivalence Chart
Storz Standard Angled Phaco Needles

Device Characteristic	Storz Standard, Angled	Storz Standard	Surgin High-Efficiency
510(k)	present	K946176	K943102
Intended Use	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.	Accessory to phaco handpiece used in lens removal.
Number of Models	Three	Three	Two
Model Variations	Needle tip bevel angle	Needle tip bevel angle	Degree angled shaft
Angled Shaft	Yes	Yes	Yes
Material(s)	Ti-6Al-4V	Ti-6Al-4V	Titanium (alloy unknown)
Recommended Surgical Incision Size (mm)	Unspecified (3.2 mm typical)	Unspecified (3.2 mm typical)	2.75
Needle I.D. (inches)	0.036	0.036	0.026
Needle O.D. (inches)	0.042	0.042	0.036
Number of Uses Recommended	Unspecified	Unspecified	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael H. Southworth, RAC
Group Manager, Regulatory Affairs
Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694

Re: K971439
Trade Name: Storz MicroFlow Plus,
Storz MicroFlow Plus Angled, and
Storz Standard Angled
Phacoemulsification Needles
Regulatory Class: II
Product Code: 86 HQC
Dated: April 16, 1997
Received: April 18, 1997

Dear Mr. Southworth:

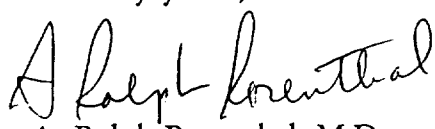
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

storz®

INDICATIONS FOR USE

Device Name: Storz MicroFlow Plus, Storz MicroFlow Plus Angled, and Storz Standard Angled Phacoemulsification Needles

Indications For Use: The Storz MicroFlow Plus, MicroFlow Plus Angled, and Standard Angled Phacoemulsification Needles are accessories to a phacoemulsification handpiece, intended for use in the ultrasonic surgical removal of the cataractous crystalline lens.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971439

Prescription Device