K051186

AUG 18 2005

Trillium Medical, Inc.
PO Box 2601
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510(k) Summary of Safety and Effectiveness

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Michael Curtis
President

510(k): K051186

Common Name: MicroPulse Phacoemulsification Console
Device Name: Unit, Phacofragmentation (21 CFR 886.4670)

Indications for Use: Phacoemulsification/extraction with ultrasonic power of cataractous lens from the eye.

Predicate Devices: The Wave Digital Phaco System (K981989)
Circuit Tree Phacoemulsifier (K954242)

Description of Device: The MicroPulse Phacoemulsification Console and foot switch, with third party accessories, will emulsify a cataractous lens and remove it from the eye, using the same technology that the predicate devices employ by using ultrasonic power. The MicroPulse Phacoemulsification Console modes of operation are similar to the predicate devices such as: Diathermy (Coagulation), U/S Phaco, Irrigation/Aspiration (I/A) and Vitrectomy. The component parts of the MicroPulse Phacoemulsification console include the console and foot switch. The U/S handpiece and tubing set are specified third party accessories. The Diathermy, Irrigation/ Aspiration, and Vitrectomy devices are universal type handpieces that are also considered additional third party accessories to the

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MicroPulse Phacoemulsification console. Trillium Medical will manufacture the console and foot switch only. Trilliums Distributers will add the third party accessories (see Exhibit B) to the console and foot switch to assemble a complete Phacoemulsification system.

Comparison: See Attachment Exhibit "A"

Conclusion: The MicroPulse Phacoemulsification Console and foot switch, when third party accessories are included(see Exhibit B), is comparable to the features of the predicated devices including technogical specifications, performance and intended use therefore we conclude that the subject device is substantially equivalent to the predicate devices listed above.

Exhibit A

Comparison Chart

Device Characteristics	*Subject Device* K051186 MicroPulse Phacoemulsification System	*Predicate Device* K981989 The Wave Digital Phaco System	*Predicate Device* K954242 Circuit Tree Phacoemulsifier
Console			
Display	LCD, Membrane switches	LCD, Membrane switches	LCD, Membrane switches
Pump	Peristaltic, no pulsation	Peristaltic, no pulsation	Peristaltic, no pulsation
Pump Vacuum Range	0 to 500 mmHg	0 to 500 mmHg	0 to 500 mmHg
Aspiration Rate	0 to 50 cc/min	0 to 50 cc/min	0 to 50 cc/min
Fluidics	External Fluid Path	External Fluid Path	External Fluid Path
System Tubing	Reusable Tubing set	Disposable/Reusable Tubing cartridge	Reusable Tubing set
Vent	Fluid Vent	Fluid Vent	Fluid Vent
Modes	Irrigation, Diathermy, U/S Phaco, I/A, Vitrectomy	Same	Same
Programmable User Parameters	Yes	Yes	Yes
Foot Switch			
Operational control	3 mode position, activates Reflux	same	same

Intended Use: Subject device has the same intended use as the predicate devices.

Design: All three devices were designed by the same engineers. The MicroPulse and The WAVE are almost identical in design. The differences have to do mostly because of their respective target markets. The MicroPulse is basically The WAVE with reduced features/Modes, to lower its costs for the low cost

international market.

Hardware/Software: All three devices share a great deal of the same hardware. The MicroPulse and The WAVE share almost identical hardware. The Circuit Tree device is hardware only, no software. The MicroPulse and The WAVE both have different embeded microprocessors, thus entirely different software.

Material specifications:

The Console and footswitch do not have any direct or indirect (e.g. fluids) patient contacting materials. Any such patient contact, direct or indirect, would be only through the third party accessories listed in 'Exhibit B'.

Mechanical and Electrical specifications:

The MicroPulse and The WAVE share the same mechanical and electrical specifications. See the MicroPulse operators manual.

Differences:

Features: The Wave has a remote control. The MicroPulse and Circuit Tree devices do not.

The Wave has a remote computer interface. The MicroPulse and Circuit Tree devices do not.

LCD Display. The Wave is 4 lines X 40 characters. The MicroPulse is 4 lines X 20 characters. The Circuit Tree has LED displays.

The WAVE has voice annunciation upon keypress. The MicroPulse and Circuit Tree devices do not.

Electronics: The circuitry of the MicroPulse and The WAVE are almost identical, with the following exceptions; They both use different embeded microprocessors, because the one used on The Wave is no

longer sold. The MicroPulse does not have voice playback electronics for cost saving reasons. The remote computer interface (serial) is too expensive for the low cost market therefore not included. In the MicroPulse the foot switch position hardware was added to replace the function that was performed in software on The WAVE. This change allows the surgeon using the MicroPulse console to have more control, such as keeping Irrigation control and the ability to continue to control the drivers if the microprocessor fails. The design in The WAVE only allowed the surgeon to shut down the drivers by taking his foot off of the foot switch if the microprocessor failed.

Software: The major differences in software design are as follows; In the MicroPulse, the microprocessor is only used for front panel user interface. This involves reading the switch matrix, displaying data on the LCD, setting the modes, setting the driver levels, and memorizing memory presets.

The Sofware design of The WAVE does not only the above front panel user interface, but, also interfaces between the foot switch and the drivers (this is done real time in hardware on both Micropulse and Circuit Tree). Software routines in The WAVE are included for the remote computer interface (serial) and voice playback, but, not on the MicroPulse or Circuit Tree. The Circuit Tree does not have a microprocessor, therefore, no software.

Electrical Safety: The circuits affecting electrical safety, Input power, power supplies, driver outputs and patient/doctor connections are identical in design with The WAVE. Electrical safety tests required by safety agency are identical and all devices are fully tested to the same requirements. Both the MicroPulse and The WAVE were designed to meet the following standards; EN60601-1, EN60601-2,UL2601-1, and CAN/CSAC22.2 No. 601.1.

Exhibit B

RECOMMENDED REUSABLE ACCESSORIES

The following accessories have been tested to be compatible with the MicroPulse console and foot switch.

Phaco Handpiece and tips

Handpiece Part Number: PH-10140, Microsurgical Technology (K953959)
Frequency (kHz) 37.5 to 40.5
Bandwidth (Hz) 250 to 400
Capacitance (pF) 1400
Stroke at full power (μ) 69 to 96
Connector – 9 pin Fisher 104 series scaled to facilitate autoclaving.

30 degree tip Part Number: PT-11030, Microsurgical Technology (K943672)
45 degree tip Part Number: PT-11045, Microsurgical Technology (K943672)

Diathermy Handpiece and Cable

Bi-Polar Pencil Part Number: 14-7000, Kirwan Surgical Products (K962678)
Bi-Polar Cord Part Number: 10-5000, Kirwan Surgical Products (K913514)

The Bipolar Diathermy Generator in the MicroPulse console is designed to use all of the currently available handpiece and cordsets designed for the phaco procedure.

Irrigation/Aspiration Handpiece and tips

Handpiece Part Number: IH-90200, Microsurgical Technology
Connectors – Irrigation, Female Luer. Aspiraton, Male Luer.

Straight tip Part Number: IH-90301, Microsurgical Technology
Curved tip Part Number: IH-90302, Microsurgical Technology
Aspiration Port size – 0.3 mm.

Vitrectomy Handpiece and Infusion sleeve

Handpiece Part Number: 12-101, M. Imonti and Associates (K950799)
Connectors – Pressure line, Male Luer with integral lock ring. Aspiration line, Male Luer.
Cutting speed – 50 to 600 cuts/min.
Pressure drive – 20 psi. Must operate at 10 psi with a residual pressure of 5 psi at 600 cuts/min.

Infusion Sleeve Part Number: 12-150-100, M. Imonti and Associates

Tubing set

Reusable pak Part Number: 013-0000-007, Circuit Tree Medical (K962430)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2005

Trillium Medical, Inc.
c/o Mr. Michael Curtis
President
PO Box 2601
19880 Caldart Avenue NE
Poulsbo, WA 98370

Re: K051186
Trade/Device Name: MicroPulse Phacoemulsification Console
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation Unit
Regulatory Class: Class II
Product Code: HQC
Dated: July 26, 2005
Received: August 2, 2005

Dear Mr. Curtis:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K051186

Device Name: MicroPulse Phacoemulsification Console

Indications for Use: Phacoemulsification/extraction with ultrasonic power of cataractous lens from the eye.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (Part 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)

DRB Nicholas

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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