K062779 Exhibit 3

Revised
510(k) Summary

OCT - 5 2006

Prepared: 21st August 2006

1. Applicant & Co-Specification Developer:	**New Wave Surgical Corporation** 625 Jackson Ave Suite A Bronx ,NY 10455 USA Tel #: 866-586-8883 Fax:#: 866-586-6793
Submitter	**New Wave Surgical Corporation**
Address	625 Jackson Ave Suite A Bronx ,NY 10455 USA Tel #: 866-586-8883 Fax:#: 866-586-6793
Trade/proprietary Name	Defogging Heated Endoscope Lens Protector
Common Names	Endoscope Anti- fogging Device
Classification name	Endoscope and/or Accessories
Classification number	21CFR 876.1500

Legally marketed devices to which we are claiming equivalence
The different components of the DHELP device are functionally equivalent to the following supplies and devices:

Predicate devices using sterile antifog solutions in laparoscopic procedures:

Endoscopic Anti Fog Device (Mister Clear)	510k Number K993604
Clear-It Anti-Fog Solution	510k Number K022826
ClearField Anti-Fog Sterile Wipe	510k Number K974454

Predicate devices that defog the laparoscope by warming the scope in a heated solution:

Applied Medical's Scope Warmer	510k Number K931895
Stryker's Scope Warmer	510k Number K053311
Deroyal Industries, Inc Defogger	510k Number K982465
OR Solution Scope Holder	510k Number K051979

Predicate devices that are disposable and use batteries to power an electrical resistance heating mechanism:

Surgical Medical Device Cautery	510K Number K023506

Predicate devices that are battery operated and disposable:
The following battery-operated device is used for laparoscopic surgeries and is disposable; much like DHELP is a small device containing batteries that is disposed after every laparoscopic surgery.

Buffalo Filter's LapEvac — 510k Number K052797
Circon Surgiflex Wave Suction-Irrigator System — 510k Number K992126

Comparison Table:

Characteristic and Material	**D.H.E.L.P**	**Clear-It Anti-Fog Solution (K)022826**	**Deroyal Industries, Inc Defogger (K)982465**	**OR Solution Scope Holder (K)051979**	**Stryker's Scope Warmer (K)053311**
Intended Use	DHELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens for 5 mm and 10 mm scopes	Clear-It Anti-Fog Solution is indicated for use in the sterile surgical arena to eliminate condensation from endoscopic lenses, microscope lenses, goggles and other devices that are likely to fog.	Is used during endoscopic, laparoscopic, gastroscopic and arthroscopic procedures to prevent fogging of endoscope lens	Is designed to hold optical end of various endoscopes above the warm solution to prevent fogging or wetting of the scope eyepiece.	Is intended to be used, prior to and during these procedures, to heat endoscopes so as to minimize fogging of the scope.
Solution	FDA approved ShurClens, a wound cleaning surfactant	Water, Isopropyl Alcohol, Sodium Alcohol Ether Sulfate, and Ammonium Dodecylbenzene	Surfactant in water and isopropyl alcohol	N/A	Sodium Acetate
Sponge	Yes	Yes	Yes	N/A	N/A
Mechanism of Action	Heating and dipping distal end of endoscope into solution	Wiping distal end of endoscope with solution using sponge	Wiping distal end of endoscope with solution using sponge	Heating	Heating
Sterility	Sterile	Sterile	Sterile	Sterile	Sterile
Reusable/Disposable	Disposable	Disposable	Disposable	Disposable	Reusable
Meets Biocompatibility standards	Yes	N/A	Yes	Yes	Yes

Device Description:
The Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.) is a small, sterile, disposable, multi-function device. It is designed to heat an anti-fog surfactant and maintains this solution above body temperature for over 4 hours. This is intended to reduce fogging better than other anti-fog methods by combining both heat and the antifog solution.

Intended Use:
DHELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Assessment of Performance:
DHELP testing was conducted with a live anesthetized pig. A Stryker 888 endoscopy system was used with a 10mm and a 5mm Stryker laparoscope, and DHELP was evaluated in a series of experiments with varying temperatures and surfactant concentrations and by comparison to the current defogging methods. DHELP was also used with 4 different laparoscope types and on Olympus, Stryker and Storz camera systems to make sure that it was functionally compatible with the most common scopes and systems. Temperature testing was conducted on DHELP device. Risk Analysis and biocompatibility testing has also been conducted.

Conclusion:
DHELP's performance was equivalent to any other conventional method evaluated. Our evaluation concluded that D.H.E.L.P raises no new issues of Safety and effectiveness.

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510(k) Summary

Prepared: August 21st, 2006

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Submitter	**New Wave Surgical Corporation**
Address	625 Jackson Ave Suite A Bronx ,NY 10455 USA Tel #: 866-586-8883 Fax:#: 866-586-6793
Trade/proprietary Name	Defogging Endoscope Lens Protector
Common Names	Endoscope Anti- fogging Device
Classification name	Endoscope and/or Accessories
Classification number	21CFR 876.1500

Legally marketed devices to which we are claiming equivalence
The different components of the DELP device are functionally equivalent to the following supplies and devices:

Substantial Equivalence:
The different components of the DELP device are functionally equivalent to the following supplies and devices:

Predicate devices using sterile antifog solutions in laparoscopic procedures:

Endoscopic Anti Fog Device (Mister Clear)	510k Number K993604
Clear-It Anti-Fog Solution	510k Number K022826 DGRND
ClearField Anti-Fog Sterile Wipe	510k Number K974454
Deroyal Industries, Inc Defogger	510k Number K982465 ULDB

Device Description:
The Defogging Endoscopic Lens Protector (D.E.L.P.) is a small, sterile, disposable, multi-function device. It is designed to store and apply anti-fog surfactant solutions to the distal lens of endoscopes. This is intended to reduce fogging on endoscopes by applying anti-fog solution to the distal lens.

Intended Use:
DELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens

Comparison Table:

Characteristic and Material	**D.E.L.P**	**Clear-It Anti-Fog Solution (K)022826**	**Deroyal Industries, Inc Defogger (K)982465**
Intended Use	DELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens	Clear-It Anti-Fog Solution is indicated for use in the sterile surgical arena to eliminate condensation from endoscopic lenses, microscope lenses, goggles and other devices that are likely to fog	Is used during endoscopic, laparoscopic, gastroscopic and arthroscopic procedures to prevent fogging of endoscope lens
Solution	FDA approved ShurClens, a wound cleaning surfactant	Water, Isopropyl Alcohol, Sodium Alcohol Ether Sulfate, and Ammonium Dodecylbenzene	Surfactant in water and isopropyl alcohol
Sponge	Yes	Yes	Yes
Mechanism of Action	Dipping distal end of endoscope into solution	Wiping distal end of endoscope with solution using sponge	Wiping distal end of endoscope with solution using sponge
Size of endoscopes used for or accommodated by device	5mm and 10mm	5mm,10mm and all other Sizes	5mm,10mm and all other sizes
Sterility	Sterile	Sterile	Sterile
Reusable/Disposable	Disposable	Disposable	Disposable
Meets Biocompatibility standards	Yes	N/A	Yes
Level of bio-compatibility	External communicating device (Tissue/bone/ Dentrin communicating)	External communicating device (Tissue/bone/ Dentrin communicating)	External communicating device (Tissue/bone/ Dentrin communicating)
Duration of bio-compatibility	Limited	Limited	Limited

Assessment of Performance:

The functionality and compatibility of the main DELP components have been tested in trials conducted with the DHELP device. DELP is manufactured with the same stainless steel reservoir, the same ShurClens surfactant solution, the same white-balancing sponge, the same type of rubber valve, the same type of microfiber, and the same type of foam used in DHELP. All of these components functioned well in tests with DHELP and were compatible with a wide range of scopes.

DHELP testing was conducted with a live anesthetized pig. A Stryker 888 endoscopy system was used with a 10mm and a 5mm Stryker laparoscope, and DHELP was evaluated in a series of experiments with varying temperatures and surfactant concentrations and by comparison to the current defogging methods. DHELP was also used with 4 different laparoscope types and on Olympus, Stryker and Storz camera systems to make sure that it was functionally compatible with the most common scopes and systems. Temperature testing was conducted on DHELP device. Risk Analysis and biocompatibility testing is also been conducted.

Conclusion:

DELP's performance was equivalent to any other conventional method evaluated. Our evaluation concluded that D.E.L.P raises no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

New Wave Surgical Corporation
% Ms. Erin Sparnon
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K062779
Trade/Device Name: Defogging Heated Endoscopic Lens Protector (D.H.E.L.P) and Defogging Endoscopic Lens Protector (D.E.L.P)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, KOG
Dated: September 15, 2006
Received: September 18, 2006

Dear Ms. Sparnon:

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 (240) 276-0120 . 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Barbara Buchman

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not Assigned as of now

Device Name: Defogging Heated Endoscopic Lens Protector (D.H.E.L.P)

Indications for Use:
DHELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Prescription Use__X___ **AND/OR** **Over-The-Counter Use ___**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher for MJM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062779

Indications for Use

510(k) Number (if known): Not Assigned as of now

Device Name: Defogging Endoscopic Lens Protector (D.E.L.P)

Indications for Use:
DELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Prescription Use X ___ AND/OR **Over-The-Counter Use** ___
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062779