

K021985

SEP 10 2002

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## **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA**

Model No./Name: MedX LCS Laser Series

Classification: Lamp Non-heating – Section B – NHN  
Physical Medicine Device, 21 CFR 89.5500 (Class II)

Predicate Device: MicroLight 830T Laser – K010175

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

### **Description of the Device**

MedX LCS Laser Series primarily consists of a hand held portable laser device and the battery recharger. The hand held laser contains the laser diodes and assembly, circuit board, electronics, battery and labels. The power receptacle for the battery recharger is located at the base of the hand held laser.

The MedX LCS is an 830 nm infrared laser indicated for adjunctive use in the temporary management of hand and wrist pain associated with carpal tunnel syndrome. The product has been deemed substantially equivalent to the MicroLight 830T Laser – K010175.

The device meets the requirements of UL standards in United States.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MedX Electronics Inc.  
Anita Saltmarche  
Vice-President of Clinical and Scientific Affairs  
3535 Laird Road, Unit 2  
Mississauga, Ontario  
Canada L5L 5Y7

Re: K021985

Trade/Device Name: MedX LCS 090 Laser Series

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: NHN

Dated: June 15, 2002

Received: June 18, 2002

Dear Ms. Saltmarche:

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.

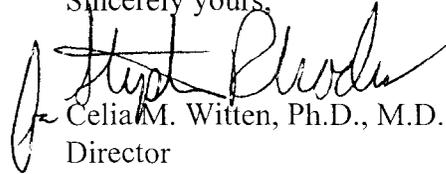
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Anita Saltmarche

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

