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5. 510(k) PREMARKET NOTIFICATION SUMMARY

(as per 21 CFR Part 807.92)

I. Applicant:

Weber Medical GmbH
Sohnreystrasse 6
37697 Lauenförde
GERMANY

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Key Contact: Dr. med. Dipl. Chem. Michael Weber
(Chairman)

II. Device Name

Proprietary Name:	weberneedle®basic laser weberneedle®basic "compact edition" laser
Common / Usual Name:	Infrared Lamp
Classification Name:	Class II, Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The weberneedle®basic laser is indicated to provide topical heating for the following:

- temporary increase of local blood circulation.
- temporary relief of minor muscle and joint aches, pains, and stiffness.
- temporary relaxation of muscles.
- temporary relief of muscle spasms.
- temporary relief of minor pain and stiffness associated with arthritis.

IV. Predicate Device

The *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* are substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. Representative predicate devices to the *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* include, but are not limited to, the Thor Int. DDII Laser System (K033923) and the Chattanooga Group Vectra Genisys Laser System (K040662). These

devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification Process.

V. Description of the Device

The *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* are non-invasive, portable therapeutic medical laser systems designed to deliver light energy to the target tissue. The red and infrared lamps provide continuous heat therapy at a fixed frequency. The System operates by AC power and is used with 8 up to 12 laser modules, as standard 4 red and 4 infrared modules. The system consists of a Control Unit / Power Supply that houses the electronics and controls the power and varies the frequency of the each laser module. The *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* are equipped with single fibre optics to bring the emitted energy to the tissue. That allows treatment either of small or of expanded pain areas as well as both at the same time.

VI. Summary of the Technical Characteristics of the *weberneedle®basic laser* as Related to the Referenced Predicate Devices.

The *weberneedle®basic laser, the weberneedle®basic "compact edition" laser* and the aforementioned predicate devices are infrared lamps as defined in 21CFR 890.5500. These devices utilize infrared and visible red diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint aches, pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local circulation and the temporary relaxation of muscle. The *weberneedle®basic laser, the weberneedle®basic "compact edition" laser* and the named predicate devices have the same intended uses and similar technical and performance characteristics.

VII. Testing

Testing of the System includes functional performance testing and electrical safety testing.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* has the same intended uses, with similar functional and performance characteristics. The *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* are designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue

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temperature reported in literature and accepted by Federal Food and Drug Administration.

The *weberneedle®basic laser and the weberneedle®basic "compact edition" laser* perform as intended and do not raise any new safety or efficacy issues.

Submitter:
Dr. med. Dipl. Chem. Michael Weber
(Chairman & General Manager)
Sohnreystrasse 6
36797 Lauenförde

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Weber Medical GmbH
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle, North Carolina 27709

AUG 11 2008

Re: K073352
Trade/Device Name: weberneedle®basic laser
weberneedle®basic "compact edition" laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ILY
Dated: July 28, 2008
Received: July 29, 2008

Dear Mr. Rongero:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

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4. STATEMENT OF INDICATION FOR USE

510(k) Number (if known) Pending

Device Name:

weberneedle®basic laser
weberneedle®basic "compact edition" laser

Indication for Use:

The weberneedle®basic laser is indicated to provide topical heating for the following:

- temporary increase of local blood circulation.
- temporary relief of minor muscle and joint aches, pains, and stiffness.
- temporary relaxation of muscles.
- temporary relief of muscle spasms.
- temporary relief of minor pain and stiffness associated with arthritis.

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!)

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

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