OCT 2 0 2011

K110912

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 820, Section 820.3

Submitter's Name:	The Daavlin Distributing Company
Registration Number:	1526255
Address:	205 West Bement Street Bryan, Ohio 43506
Telephone:	419.636.6304
Contact:	Michele Thiel
Date Prepared:	March 29, 2011
Device Trade Name:	Smart Touch Multi-Machine Software
Device Common Name:	Multi Machine Software
Device Classification:	Class II
Product Code:	FTC
Regulation Number:	CFR 878.4630
Regulation Name:	Ultraviolet treatment for dermatologic/skin disorders
Predicate Device:	Daavlin Distributing Company Spectra 3 Series PC & SP Ultraviolet Phototherapy Cabinet K063621

Device Description:

The Smart Touch Multi Machine Software is used to control multi phototherapy devices from a custom built computer containing a UV3001 interface board supplied by Daavlin (schematics located in Device Specification of this 510(k) submission), with spectral output at peak wavelengths of 311 nm (Narrow Band UVB) and 350 nm (UVA). An "off the shelf" replacement is not possible. Replacement can ONLY be obtained by Daavlin. It is intended for use by or under the direction of a physician, for the treatment of diagnosed skin disorders such as psoriasis, vitiligo, and atopic dermatitis (eczema).

Predicate Device Comparison:

The Smart Touch Multi Machine Software is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV lamps) and materials of identical composition. The Smart Touch Multi Machine Software's only variation from the predicate device, is in that the control system hardware and software has been updated to utilize current technology and control multiple units. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principals of the Smart Touch Multi Machine Software are the same as those of the predicate device.

Intended Use:

"The Smart Touch Multiple Machine Phototherapy System can be connected to the following Daavlin models:

3 Series Models 311-48, 311-24, 311/350-24/24, 350-48, 350-24

M Series Models 311-10, 350-10, 311/350-04/06

The Smart Touch Multiple Machine Phototherapy System is a medical ultraviolet light source system, which is intended for use by or under the direction of a licensed physician for the treatment of psoriasis, vitiligo and atopic dermatitis (eczema) on all skin types (I-VI)."

Performance Data:

The Daavlin Smart Touch Multi Machine Software performance data is the same as or very similar to that of the claimed predicate device. The control system hardware used is the same.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the Smart Touch Multi Machine Software is substantially equivalent to the legally commercialized predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2011

The Daavlin Distributing Company
% Ms. Michele Thiel
205West Bement Street
Bryan, Ohio 43506

Re: K110912
Trade/Device Name: Smart Touch Multi-Machine Software
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: September 21, 2011
Received: September 27, 2011

Dear Ms. Thiel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

/S/ Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number

Device Name Smart Touch Multi-Machine Software

Indications for Use

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Prescription Use _X_ OR Over-the-Counter Use ___

(per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110912