

BOYD INDUSTRIES, INC.
12275 75th Street North • Largo, Florida 33773 3031
813-536-3592 • 1-800-255-BOYD • FAX 813-530-3853

AUG 14 1997

K971941

(10) 510 (k) Summary

Submitter's Name: Boyd Industries, Inc.
12275 75th Street North
Largo, FL 33773

Phone Number: (813) 536-3592
(800) 255-2693

Fax Number: (813) 530-5853

Contact Person: Mr. Bruce V. Livingston

Date of Summary: May 23, 1997

Trade Name: Aqua Spray

Common Name: Electric Hand piece

Classification Name: Dermatome (Industry code 79)

Legally Marketed device of Equivalence: Podo Spray

Device Description: The Aqua Spray is an electrically powered accessory to a burr. The Aqua Spray enables a burr to be attached to an electric hand piece capable of 30,000 rpm, in each direction. A small reservoir in which a 50% distilled water and isopropyl alcohol is placed is included in the unit. A small air pump sprays the water/alcohol liquid in a fine mist on the burr. The mist cools the area and prevents nail dust from the treatment area to become airborne.

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Device Use:	The Aqua Spray is intended for use in an office based environment. The target market of this device is podiatry. The Aqua Spray is an accessory to a manual burr. The Aqua spray provides an electrically powered hand piece that provides the burr a faster more efficient method of debriding fungus from the nails of the toe.
Technological characteristics:	The technological characteristics between the Aqua Spray and the Podo Spray are virtually identical. Both devices use an electric hand piece, air pump to create mist, PC board control of the unit, 110 volt AC power, foot control capability, variable flow of mist, master on/off switch, left/right rotation capability of hand piece (burr), on/off capability of spray. A wiring schematic and component list is included for reference with the Podo Spray.
Non-clinical tests:	Not applicable
Clinical tests:	Not applicable
Test summary:	Not applicable



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce V. Livingston
Boyd Industries, Inc.
12275 75th Street North
Largo, Florida 33773-3031

AUG 14 1997

Re: K971941
Trade Name: Aqua Spray
Regulatory Class: II
Product Code: GEY
Dated: May 23, 1997
Received: May 27, 1997

Dear Mr. Livingston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

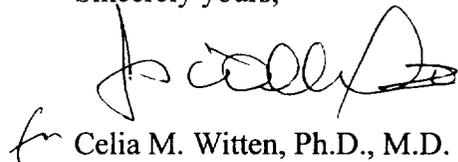
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Bruce V. Livingston

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

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

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

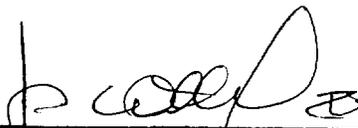
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510 (k) Indications For Use Statement

The Aqua Spray is intended for use by Podiatric professionals as an accessory to a burr. The Aqua Spray provides an electric hand piece with an attachment that provides a fine mist of isopropyl alcohol and distilled water (50% concentration) to be dispensed over the burr. The purpose of this mist is to cool the burr and treatment area. In addition, the mist wets the treatment area, thus minimizing the amount of nail dust that becomes airborne during the nail debridement procedure.

Prescription Use _____
(Per 21 CFR 801.109)

X



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

2971941