AUG 0 8 2002

K020833

510(k) SUMMARY

1) **Boyd Industries, Inc.**
12900 44th Street North
Clearwater, FL 33762 US
Phone: 727-561-9292
Fax: 727-561-9393
Contact: Bruce Livingston
Establishment Registration Number: 1062917 (reference next page)
Date of Submission: March 8, 2002

2) **Trade Name:** Boyd Delivery Units
Common Name: Delivery System
Classification Name: Dental Operative Unit and Accessories

3) **Equivalent Device:**
The Boyd Delivery Unit is substantial to similar Dental Operative Unit and Accessories previously cleared with the FDA for marketing in the United States, using the same basic technology, design process and attention to safety. Copies of product literature are included in Section 1 and Comparison Data is included in section 2 of this submittal.

4) **Technical Description:**
The Boyd Delivery Unit is a Dental Operative Unit that provides the dentist with primary requirements for a dental operatory. The delivery system is designed to be used as an interface device to connect the dental operatory hand instruments to the appropriate supply utility such as air, water suction, drain and electricity. It functions as a system management device that provides a method of operating various hand instruments from a single control input device. The unit is furnished with controls that allow the dentist or operator to set the air pressure and water flow to the hand pieces and the syringe in the delivery head. The unit is of a stackable design providing a base for dental tools and accessories. Assistant's instrumentation delivery system, water heater, and the cuspidor are all features that this unit can offer.

5) **Intended use**: The Boyd Delivery Unit is intended to supply utilities to and serve as a base for dental tools and accessories. The use of this device does not differ significantly from the predicate dental operative units.

6) **Comparison of device to marketed devices**
Reference chart "Comparison of device to marketed devices" on the following page.

Establishment Name:
BOYD INDUSTRIES, INC.
12900 44TH STREET NORTH
CLEARWATER, FL 33762
Establishment Registration Number: 1062917
Establishment Operations: Contract Manufacturer
Establishment Status: Active
Date of Registration Status: 2001

Owner/Operator:
BOYD INDUSTRIES, INC.
12900 44TH STREET NORTH
CLEARWATER, FL 33762
Owner/Operator Number: 9030301

Official Correspondent Name: MR. BRUCE LIVINGSTON
Official Correspondent Phone Number: 727-561-9292
Official Correspondent Firm:
BOYD INDUSTRIES, INC.
12900 44TH STREET NORTH
CLEARWATER, FL 33762

Listing from FDA Website

Comparison of device to marketed devices

Feature	Boyd Industries, Inc.	a-dec (K000966)	DentalEZ (K931204)	Marus Dental
Mounting unit	Cabinet	Cabinet	Cabinet	Cabinet
Instruments Available	High-speed handpiece hookup, low speed handpiece hookup, 3-way syringe, saliva ejector, high volume evacuation with solids collector	High-speed handpiece hookup, low speed handpiece hookup, 3-way syringe, saliva ejector, high volume evacuation with solids collector	High-speed handpiece hookup, low speed handpiece hookup, 3-way syringe, saliva ejector, high volume evacuation with solids collector	High-speed handpiece hookup, low speed handpiece hookup, 3-way syringe, saliva ejector, high volume.
Activation	Master off/on valve, handpiece toggle switch and foot control	handpiece toggle switch and foot control	Master off/on valve, handpiece toggle switch and foot control	Automatic activation for each handpiece
Cleaning	Air flush system	Water flush	Water flush	Water flush
Water System	Self contained	Self contained	City hook up or self contained	City hook up

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 8 2002

Mr. Bruce Livingston
Boyd Industries, Incorporated
12900 44th Street North
Clearwater, Florida 33762

Re: K020833
Trade/Device Name: Boyd Delivery Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: June 14, 2002
Received: June 27, 2002

Dear Mr. Livingston:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020833

Page ___ of

510(k) Number (if known):

Device Name:

Indications For Use:

Boyd delivery systems are intended for use by Dental Professionals for effective treatment of patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K020833