K983285

Engle Dental Systems

NOV 4 1998

P.O. Box 725 • Forest Grove, Oregon 97116 U.S.A. • 503/359-9390 • FAX: 503/357-7286 •

510 (k) SUMMARY

Engle Dental Systems, Inc.
4115 24th Ave, Suite A
P.O. Box 725
Forest Grove, OR 97116
Registration Number: 3020989
Establishment Type: Manufacturer

Contact Person: Marvin Fox
Official Correspondent
Tel: (503) 359-9390
Fax: (503) 357-7286

Date Prepared: August 31, 1998

Trade Name: Engle Dental Systems Family of Dental Units

Unit Style	Various Engle Dental Part Numbers*
AS-1 Delivery System	P070865, P070867, P070869, P070871, P070873, P070875, P070876, P050120
AS-2 Delivery System	P070878, P070880, P070882, P070883, P070885, P050125
EDS-1 Delivery System	P071900, P071902, P071904, P071906, P071908, P071934, P070886, P071935
ME-2 Delivery System	P070840 through P070847, P070850 through P070857, P070860 through P070863, P070092, P070093, P050108, P050109, P050114, P050115
ME-2 Control Head Only	P050135, P050145, P071855 through P071862
Micro II Miniature Control	P028101, P028115

*Note: Please see matrix of parts (pages 19-20) for exact descriptions of each part number listed above. The different part numbers represent variations on the common control head styles. For example, the P071900 is an EDS-1 Delivery System with an ASC 101 cuspidor, while the P071902 is an EDS-1 Delivery System with an ASC 102 cuspidor. The difference between these two parts is the plastic housing on the cuspidor. The other part numbers contain similar design differences. Looking at the engineering drawings in Sections A, B, C, E, & M, it is clear that these differences are cosmetic and not technological in nature.

Common Name: Dental units
Classification Name: Unit, operative, dental (per 21 CFR 872.6640)

Sec. 872.6640. Dental operative unit and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 1998

Mr. Marvin Fox
Official Correspondent
Engle Dental Systems, Incorporated
4115 24th Avenue, Suite A
P.O. Box 725
Forest Grove, Orlando 97116

Re: K983285
Trade Name: Engle Dental Family of Delivery Systems
Regulatory Class: I
Product Code: EIA
Dated: August 31, 1998
Received: September 18, 1998

Dear Mr. Fox:

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 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). 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 (Premarket 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.

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) 594-4692. 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" (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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K983285

Device Name: Dental Delivery System

Indications for Use:

The Engle Dental Systems Family of Dental Units are medical devices to be used by dentists, technicians, and hygienists in dental procedures. The units will deliver air and water to the ends of the hand pieces that the dentists use in the procedures they perform on their patients. It is designed to operate dental handpiece attachments and suction instruments. The Engle Dental Systems Family of Dental Units feature numerous customer-requested options such as in-line air and water filters, special foot controls, assistant's arms.

The Engle Dental Systems Family of Dental Units is substantially equivalent to the 1400 XL Deluxe Dental Delivery System manufactured by Summit Dental Systems in Ft. Lauderdale, FL. Engle Dental Systems is the manufacturer of the Engle Dental Systems Family of Dental Units and supplier all of the parts related to the construction and maintenance of the dental units.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983285