



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Mr. David R. Cole
General Manager
Lite Specialty Metal Works, Incorporated
20460 S.W. Avery Court
Tualatin, Orlando 97062

Re: K984609
Trade Name: ADEC Dental Unit, Models Century Plus &
Cascade, DCI Dental Unit
Regulatory Class: I
Product Code: EIA
Dated: December 4, 1998
Received: December 28, 1998

Dear Mr. Cole:

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.

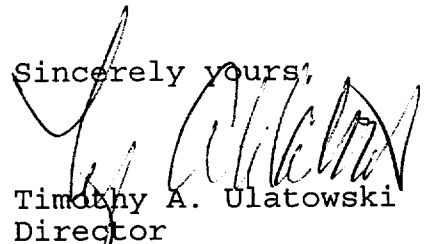
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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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" (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,



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

Enclosure

K984609**LSM**
WORKS**LITE SPECIALTY
METAL WORKS, INC.**510 (K) NUMBER: K984609DEVICE NAME: LSM DENTAL UNIT

INDICATIONS FOR USE:

The LSM Dental Unit is intended to supply power to and serve as a base for other dental services. The Dental Operative Unit includes an automatic control system, a water control for hand pieces and syringes, a 3 way syringe, instrument holder, mounting, vacuum system, foot control and utility box.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Over-The-Counter-Use

Prescription Use ✓
(Per 21 CFR 801.109)Susan Ruvoes
(Division Sign-Off)Division of Dental, Infection Control,
and General Hospital Devices510(k) Number K984609

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