DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2003

Mr. Thomas J. Louisell
Regulatory Affairs Scientist
A-dec, Incorporated
2601 Crestview Drive
Newberg, Oregon 97132-9257

Re: K022816
Trade/Device Name: W & H Lisa Steam Sterilizer
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 3, 2002
Received: December 6, 2002

Dear Mr. Louisell:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Corrected

510(k) Number (if known): K022816

Device Name: W&H Lisa Steam Sterilizer

Indications for Use:

The W&H Lisa Water Steam Sterilizer is designed for pressurized steam sterilization of medical and dental instruments (wrapped and unwrapped), including complex lumened devices (such as dental handpieces), porous and hollow loads.

It has the following automated program cycles:

Two Sterilization Cycles (summaries):

	B Standard 273 Cycle	**B Standard 250 Cycle**
Max Temperature	273 °F	250 °F
Duration of sterilization	4 min	30 min
Pressure	31.5 psi	17 psi
Duration of drying	15 min	20 min
Total cycle time empty	30 min	65 min
Total cycle time full load	40 min	75 min
Uses:		
Full solid load	Yes	Yes
Full porous textile load	Yes	Yes
Small porous items	Yes	Yes
Dental Handpieces	Yes	Yes
Unwrapped material	Yes	Yes
Single/double wrapped	4.5 lbs max. wrapped	4.5 lbs max. wrapped
Liquids	No	No

Two Test Cycles (summaries):

	Bowie & Dick	**Vacuum**
Max Temperature	275.9 °F	None
Duration of sterilization	3 min 20 sec	None
Max Pressure	31.5 psi	-12.3 psi
Duration of drying	4 min	None
Test period	N/A	10 min

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

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

510(k) Number: K022816