LYSTA

K992236

AUG 27 1999

510(k) SUMMARY

A. Submitter Information

Lysta A/S
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Denmark

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Contact Person: Erling Mortensen
Quality Coordinator

Date Prepared: June 28, 1999

B. Device Identification

Common/Usual Name: Polymerization Light-Curing Device
Proprietary Name: LCxx00 Compacta consisting of:
LC2500 Compacta
LC4000 Compacta
LC6000 Compacta
LC8000 Compacta

C. Identification of Predicate Device

The LCxx00 Compacta is substantialy equivalent to its predicate device the Lysta LC2500 C/BA (K991138) previously cleared and currently marketed.

D. Device Description and performance data

LCxx00 Compacta lamp is a polymerization lamp which provides light primarily in the range between 400 - 515 nm and is capable of curing light-cured dental materials. It is a component intended for integration in a standard dental unit and the light source is supplied with power from the unit. Compressed air for cooling of the handpiece is also provided from the unit.

The LCxx00 Compacta lamp is supplied with a 25 Watt, 40W, 60W or 80W halogen bulb. The visible light from the bulb is filtered to provide a wavelength between 400 and 515 nm which is directed to a light guide with an 8mm diameter. Light in this wavelength range is able to cure light composit material used for dental fillings.

The output from the LCxx00 Compacta through the autoclavable, detachable light guide is approximately 530 mW/cm^2 , 750 mW/cm^2 , 1080 mW/cm^2 , 1440 mW/cm^2 respectively, in total. Within the range of 400 - 515 nm the lamp has an output of approx. 390 mW/cm^2, 590 mW/cm^2 , 825 mW/cm^2 , 1180 mW/cm^2 respectively. These measurements are carried out according to requirements in ISO/DIS 10650.2.
This light cures the restorative composite materials to a depth of about 5.5 mm, 5.7 mm, 6.0 mm, 6.7 mm respectively in 40 seconds. The composite is cured 100 % to a depth of 2.4 mm, 2.5 mm, 2.7mm and 3.1 mm respectively.

The halogen bulb is built into a handpiece which is ergonomically shaped so that it is comfortable and easy to use for a dentist. The housing of the handpiece is made of thermoplastic material. Excessive heat is cooled by air from the dental unit and if the cooling air should fail, a built in thermal fuse and a thermal switch will disconnect the electrical connection.
The LCxx00 Compacta is supplied with power and with air from the dental unit via a cable. This cable has a connector so that it is detachable from the handpiece.
The handpiece contains a bayonet-like connector which enables the front section to be detached from the rear section so that the halogen bulb and the light filter can be exchanged by the user.

E. Substantial Equivalence

The LCxx00 Compacta is, in relative technical terms, almost identical to the predicate device. Relative technical and physical differences are insignificant and are not relevant with regard to safety and effectiveness during use. The smallest of the four Compacta lamp versions (LC2500 Compacta) is identical to the predicate device as far as capacity is concerned.

F. The Product's Use

The LCxx00 Compacta will be used as a component to be integrated into a dental unit and will be marketed as an integral part of the dental unit.
The function of the lamp on the unit is to polymerize dental composite materials for restoration of cavity preparation, curing of bonding and other photo-curing restorative materials as well as any application where a conventional dental curing light would be used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

Mr. Gregers Lystager
Managing Director
Lysta A/S
Gammelgaardsvej 102
DK-3520 Farum
Denmark

Re: K992236
Trade Name: Lysta LC Compacta Curing Light, Models LC2500 Compacta, LC4000 Compacta, LC6000 Compacta LC8000 Compacta
Regulatory Class: II
Product Code: EBZ
Dated: June 28, 1999
Received: July 2, 1999

Dear Mr. Lystager

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 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" (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

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K992236

INDICATION FOR USE

510 (k) Number (if known):

Device Name: Lysta LCxx00 Compacta consisting of:
LC2500 Compacta
LC4000 Compacta
LC6000 Compacta
LC8000 Compacta

Indications for use:

- Polymerization of light-cured dental materials
- Polymerization of restorative composite materials

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992231