1. 510 (k) Summary and/or Certification Statement in accordance with Safe Medical Devices Act of 1990:

Getinge/Castle, Inc. 3000 Series surgical lamps are designed to provide the high quality lighting required in an operating room environment. The standard configuration shall be a two lamp head system. Two sizes of lamp head will be offered, a 24" diameter and a 32" diameter.

There are four major considerations in the design of the surgical lamp systems:

1. Infra-red and Ultra-violet filtration will exceed the specifications as set forth by IEC 601-2-41.

2. Color Representation, as measured by Color Rendering Index and color temperature, will meet or exceed the specifications of IEC 601-2-41.

3. Light delivery, upon failure of one bulb, will continue to be >70% intensity.

4. Electromagnetic and Bacteriological Neutrality – The product has been designed, and will be tested, to comply with the electromagnetic compatibility requirements of the European Medical Device Directive. The sealed optical unit, the flat smooth surfaces, and the touch-controls provide for an aseptic interface. The lamp head is designed to provide limited interruption of laminar air flow.

The lighting systems are supported by specifically designed, steel and aluminum, load bearing drop tubes, yokes, and counterbalance arms. These assemblies are either covered with chemically resistant plastic, or coated with epoxy resin paint. The structures are mechanically connected at pivot points housing fiber optic connection joints. The lamp heads are able to be positioned in virtually any orientation, with no drift once positioned.

The light source is an assembly comprised of eight metal halide light bulbs, a dichroic reflective surface to absorb ultra-violet and infra-red radiation, and fiber optic bundle connection points. Color correction is provided by Light Emitting Diode bundles which are mixed with the feed line. These bundles are controlled through an electronic sensor/comparator loop to provide constant, correct color temperature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 1999

Mr. Peter L. Koste, Jr.
General Manager
Getinge/Castle, Inc.
7371 Spartan Boulevard, East
P.O. Box 40488
North Charleston, South Carolina 29423-0488

Re: K993242
Trade Name: Castle 3000 Surgical Lamp
Regulatory Class: II
Product Code: FSY
Dated: September 24, 1999
Received: September 27, 1999

Dear Mr. Koste:

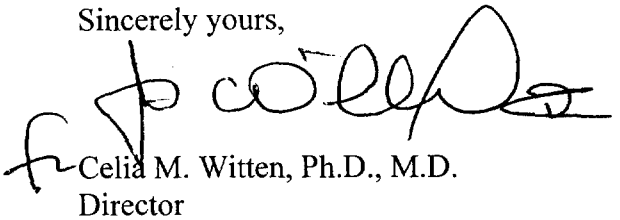
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 current Good Manufacturing Practice requirement, 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K993242

DEVICE NAME: Castle 3000 Surgical Lamp

INDICATIONS FOR USE:

The Castle 3000 Surgical Lamp is to be used to provide illumination appropriate for examination, trauma, and surgical procedures.

(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 General Restorative Devices
510(k) Number K993242