ELEKTA

Telefax

To:	Mr. William Slocumb	**Telefax Number:**	362-2653
From:	Richard S. Grome	**Copy:**	Catherine Gilmore, President Martin Knotts, Project Manager Sverker Glans, Vice President - Quality and Regulatory Affairs
Date:	November 22, 1995	**Number of Pages Including This:**	2
Re:	Leksell Gamma Unit Model 23004, Type B		

Dear Bill:

Attached please find the acceptance of the FDA of our 510(k) submittal to market the Leksell Gamma Unit Model 23004, Type B in the United States.

I believe this completes our file for the State of Georgia registration. I will give you a call on Monday, November 27th, to discuss.

Best regards,

Richard S. Grome

RSG/jsh:slocumb

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1995

Richard S. Grome
Elekta Instruments, Inc.
8 Executive Park West
Atlanta, Georgia 30329

Re: K924849
Leksell Gamma Unit Model 23004, Type B
Dated: August 2, 1995
Received: August 22, 1995
Regulatory class: II
21 CFR 892.5750/Procode: 90 IWB

Dear Mr. Grome:

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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the 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 may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health