James G. Ledbetter, Ph.D./Commissioner



Radiological Health Section, Suite 600 878 PEACHTREE STREET, N.E. / ATLANTA, GEORGIA 30309

November 18, 1985

John D. Maiers Hansell & Post 56 Perimeter Center East, N.E. Fifth Floor Atlanta, Georgia 30346-2283

Dear Mr. Maiers:

This is in reference to your application for Device Registration of the Leksell Gamma System. Our review of the application is completed. Approval of the device and issuance of a registration is pending until our receipt of documentations of approval of the sealed sources to be used in the Leksell Gamma System. We anticipate to provide you with a draft registration by the end of December 1985.

Thank you for your cooperation in this matter.

If you have any questions, feel free to contact our office at (404) 894-7627.

Sincerely,

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Thomas E. Hill, Chief Radioactive Material Unit Radiological Health Section

TEH/CAS/ln