

LaserSonics

Heraeus LaserSonics, Inc. 575 Calderwood Drive Milpitas, CA 95035 7033 (408) 954 4040

June 12, 1991

Michael H. Wynn, D.P.M.
8300 Waterbury, Suite 420
Houston, TX 77055

Dear Dr. Wynn:

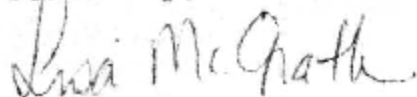
Stu Harman requested that I send you a copy of our FDA "substantial equivalence" letter which allows us to now market our CO₂ Laser and ArthroGuide[®] CO₂ Laser WaveGuide Delivery System for arthroscopic surgical treatment of the elbow and ankle. This "clearance to market" was obtained on May 6, 1991; the 510(k) number is referenced in the upper right corner of the letter.

In addition, I am enclosing our "Professional Labeling" for orthopaedics which specifically states the indications and uses of our CO₂ Lasers and WaveGuide Delivery Systems in orthopaedics.

This clearance would not have been possible without the preclinical work that you did for us on soft tissue and cartilage of the ankle. Your prompt response and efficiency in completing this project was invaluable! Thank you for helping us achieve this important milestone.

If you need any further information, or clarification on the enclosed documents, please do not hesitate to contact me.

Sincerely,



Lisa McGrath,
Regulatory Data Analyst

enc.

cc: Stu Harman

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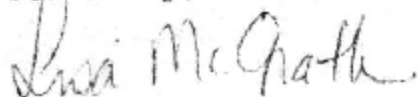
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