

SPECTRUM INTERNATIONAL, INC.

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ADDENDUM

to 510(k) Premarket Notification submission filed on July 17, 2006 for *PROMETHEY* surgical diode laser, approved on September 18, 2006, 510(k) Number: K062071

Due to consumer inquiries on a miniature version of *PROMETHEY* diode laser, a G1-04MP version was developed with much smaller housing and slightly increased maximum output power. This was possible because of use of external AC/DC power supply instead of internal AC/DC open frame power supply. This change made the device even safer for practical use due to removal of 120 VAC circuitry from the device housing. The front keypad and controller circuit board were made substantially similar to *PROMETHEY* parts. The 4 Watt laser module is similar to *PROMETHEY* laser module. Its maximum power is still under power values for predicate devices: 5W for Odyssey 2.4G and 10W for LaserSmile. Besides indicated modifications, no other changes were made to labeling, technology, performance or materials. Obviously, these changes did not effect the effectiveness and performance of the device but improved its electrical safety. The modified version of the laser is marketed under the name "Beamer STL".

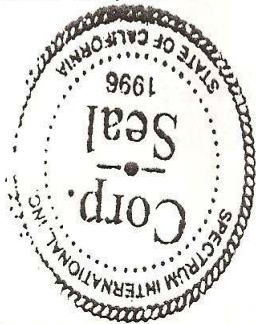
According to FDA regulations, "manufacturers need to submit a new 510(k) only when a change, or the sum of the incremental changes exceeds the §807.81(a)(3) threshold, could significantly affect the safety or effectiveness of the device." CDRH 510(k) Memorandum #K97-1 recommends to follow a flowchart for a particular change to decide whether or not to file a new 510(k). The attached Flowchart B clearly indicates that the above mentioned device changes do not require a new 510(k) submission.

George I. Bekov
President
Spectrum Int'l, Inc.



(Signature)

01-12-09
(Date)



Attachment: Flowchart B (1 page).