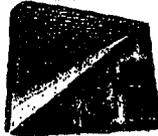


MEMORANDUM



7002 00 JUL 18 2000
BIOLASE Technology, Inc.
DENTAL, AESTHETIC AND SURGICAL LASERS

June 12, 2000

Dockets Management Branch (HFA)-305
Food and Drug Administration
12420 Parklawn Dr.
Rockville, MD 20857

cc: Cory Tylka, Office of Compliance, CDRH

Subject: Submittal of Application for Variance

Dear Director:

This memo plus the attached material constitutes the application for variance for the Twilite™ Dental Diode Laser. This application for variance is based on CDRH feedback to the Initial Product Laser Report (reference Accession Number: 0020492-00) by BIOLASE Technology, Inc submitted on March 20, 2000. The Twilite™ Dental Diode Laser is a surgical instrument designed for a variety of oral soft tissue procedures and is intended for use by general dentists and periodontists.

BIOLASE is requesting a variance for a period of 5 years. The variance request is referenced to CFR 1040.11.a.1 for BIOLASE's Class IV medical laser product. Specifically, we are requesting a variance to the requirement to monitor the patient treatment beam via an optical monitoring method called out in CFR 1040.10.e.2. BIOLASE's Twilite measures electrical current to determine the energy level of the patient treatment beam as opposed to utilizing an optical or photodiode monitoring method. BIOLASE's justification and description of advantages in using electrical current monitoring verses an optical monitoring system are detailed in attachments 1 of this document.

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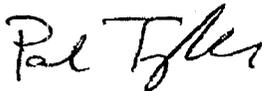
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VAR 1

BIOLASE's position is that there are clear advantages to monitoring the current with software. The software provides a more reliable and safe way of control and can ensure better management of the system in the instance of a failure event as detailed in attachment 2. Please refer to attachments 1 and 2 for a detailed explanation of how the monitoring of current provides a reliable, state-of-the-art method for ensuring a suitable means of radiation protection for the patient and operator.

Regards,



Paul Trujillo
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