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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Mr. Paul Clark
Quality & Regulatory Affairs Manager
Norwood Abbey Ltd.
63 Wells Road
Chelsea Heights, Victoria
3184 Australia

Ref: FDA Docket No. 02V-0415 Sup1
Accession No. 02A2511-02

Dear Mr. Clark:

This is written in response to your December 24, 2003, laser product report, Accession Number 0212510-02, on the Model LAD-06 Er:YAG laser product and the November 6, 2003, correspondence requesting extending the approved variance covering the Model LAD-01 laser to the LAD-06 laser, variance number 02V-0415.

We are approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Norwood Abbey Ltd., dated November 6, 2003, for a variance from the requirements of 21 CFR 1040.10(f)(3), 1040.10(f)(4), and 1040.11(a)(1) of the Federal performance standard for laser products to incorporate a remote interlock connector, key control, and a means of measurement and indication of the radiation level. This variance will allow the introduction into commerce of the LAD-06 Er:YAG Laser System manufactured by Norwood Abbey Ltd., as identified in paragraph D below under the conditions stated in paragraph F.

A. Variance Number

02V-0415

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated 5 years from the date of this letter.

02V-0415

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D. Laser Product for Which Variance is Granted

This variance is granted for the LAD-06 Er:YAG laser.

E. Provisions from Which Variance is Granted

The variance is granted from provisions of 21 CFR 1040.10(f)(3) of the performance standard for laser products requiring that each Class IIIb and Class IV laser product incorporate a remote interlock connector such that when its terminals are not connected, human access to the laser radiation greater than Class I is prevented.

The variance is also granted from provisions of 21 CFR 1040.10(f)(4) of the performance standard for laser products requiring that each Class IIIb and Class IV laser product incorporate a key control on the portable laser handpiece.

The variance is also granted from provisions of 21 CFR 1040.11(a)(1) of the performance standard for laser products requiring that each Class III and Class IV medical laser product incorporate a means for the measurement and indication of the level of the laser radiation intended for irradiation of the human body. This section requires that the means have an error in measurement of no more than 20 percent.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in item E above, the following conditions shall apply to the LAD-06 Er:YAG laser manufactured under this variance:

1. The laser will utilize a disposable tip that includes a tip interlock and tip present switch. The LAD-06 cannot function without the disposable tip fitted correctly in place and fully depressed against the skin (the target).
2. In addition to the base incorporating a compliant key switch, the portable handpiece incorporates an on-off power switch, an 'energize' button, and a trigger switch that must be pressed before the laser can fire.

3. The LAD-06 will measure the stored energy pumped into the laser module and control the output within a specified tolerance. If the energy is too high or too low, the laser defaults to a fail-safe position. Furthermore, the unit energy level is factory preset, and annual calibration checks are to be performed.

G. Basis for Approval of Variance

CDRH has determined, in accordance with 21 CFR 1010.4(a)(1), that the laser product, the LAD-06 Er:YAG laser, incorporates alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard.

As an alternative to a remote interlock connector the product incorporates the disposable tip and related internal controls including a tip interlock and a tip present switch. These design features ensure that the LAD-06 will not energize unless the required sequence of events is performed by the operator in correct order. The sequence includes: fitting the tip correctly, activating the tip present switch, pressing the energize button, waiting for the unit to charge (25 seconds), pressing the tip fully against the treatment site (which activates a microswitch and releases the beam attenuator, allowing the trigger to become active), and firing the unit. Only when both the microswitch has opened the shutter and the operator presses the trigger switch will the beam be emitted. Since the beam cannot emit unless the target is in position pressed against the disposable tip, the unit is energized, and the trigger is depressed, the internal safety shutter is believed to constitute an equivalent degree of safety as a remote interlock connector.

As an alternative to a key control, there are three on-off controls on the LAD-06 that are designed to prevent inadvertent firing of the laser: the on/off button must be turned on, the energize button must be pressed, the tip must be pressed onto the target area, and the trigger must be pressed. Once the laser is energized, it will time out in one minute, requiring the start-up procedure to be repeated. In addition, once the tip is depressed on the skin, the unit will time out in 5 seconds. The LAD-06 is intended for use by professional healthcare personnel only, who will be trained in the proper sequence required to operate the device, thus providing the equivalent security of a key control.

As an alternative to a means of measurement and indication of the radiation level, the LAD-06 incorporates a redundant internal measurement system to measure and control the stored energy pumped into the laser module. Energy levels outside tolerances would cause the laser to default to a fail-safe position, preventing the laser from firing. There is no provision or need for the operator to adjust this setting, thus making an indication of the measurement unnecessary. Laser output levels are set during manufacturing and are not adjustable. Annual recalibration by trained service personnel is required. Therefore, it is believed that the system provides safety equivalent to the safety that would be provided by a completely compliant means of measurement and indication of the radiation level.

However, please note that, due to the absence of radiation level measurement capability, we strongly recommend that your firm implement postmarket monitoring of service and complaint records to ensure stability in the preset voltage levels and as validation of the appropriateness of the chosen levels for the device's intended uses.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state:

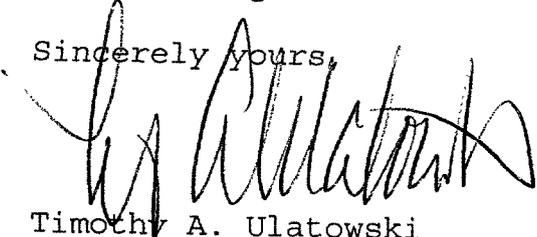
"This product is in conformity with performance standards for laser products under 21 CFR 1040, except with respect to those characteristics authorized by Variance Number 02V-0415 effective December 3, 2002.

This variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration (FDA), and a notice of availability will be published in the FEDERAL REGISTER. The variance will remain in effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

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If you have further questions on these requirements, please contact Cory Tylka of the Electronic Products Branch at (301) 594-4654, or email at cst@cdrh.fda.gov.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health