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November 6, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Att: Cory Tylka
General Surgery Devices Branch
Division of Enforcement III
Office of Compliance

Dear Cory

**Modifications to Laser Assisted Delivery Device (Epiture™ Easytouch)
Model numbers: LAD-01 & LAD-06
Accession Number 02A2511 & Variance 02V-0415**

Please be advised that the Laser Assisted Delivery Device LAD-01 has been modified to increase the ablation area (spot size) from 3mm to 6mm. The new model number is the LAD-06.

The intended use, fundamental technology and importantly, the energy density (fluence) have not changed (3.5 J/cm^2). The main differences between the LAD-01 and the LAD-06 are as follows:

- a) The spot size for the LAD-06 has been increased from 3 mm diameter to 6 mm diameter.
- b) To maintain the fluence at 3.5 J/cm^2 , the energy output has increased from 250mJ to 1J).
- c) The increased energy output has resulted in additional changes to the HV circuitry.
- d) The disposable tip has been modified to accommodate the larger aperture (3mm to 6mm).
- e) Minor changes to software to modify the energy output and model change.

The fundamental technology has not changed, including the same:

- Fluence (3.5 J/cm^2), i.e. that same safety and efficacy characteristics.
- Battery operated, portable handheld 2940nm Er:YAG laser design.
- Modular design including laser module, control module, HV module, LCD Module, trigger module, and battery module.
- Intended use.

02V-0415

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NOTE: As part of Norwood Abbey's Design Control process the LAD-06 specifications were revised and verified to meet the requirements of:

- IEC 601-1
- IEC 601-1-2
- IEC 601-2-22
- ISO 10993
- IEC 60825
- CRF 1040.10 & 1040.11 (except for variances under 02V-0415)

In support of this letter, please find attached:

- Attachment 1: User Manual (labels included in section 10).
- Attachment 2: Risk Analysis for LAD-06.
- Attachment 3: LAD-06 Test certificates.

Please note that the LAD-01 & LAD-06 will now be sold under the brand name of *Epiture™ Easytouch*.

Please contact me if you require further information or have any questions.

Sincerely yours,



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