American Dental Technologies

510(k) Summary

K961269

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Device Name:

Trade Name:	**PulseMaster**
Common Name:	**Dental Laser System**
Classification Name:	**Surgical Laser System**
Indication for Use	**Sulcular Debridement** [redacted]

Submitter:

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This 510(k) Premarket Notification is for a new indication for use for the legally marketed PulseMaster laser family. The use of the PulseMaster laser for sulcular debridement and bacterial reduction is substantially equivalent to the use of the PulseMaster laser for ablation, incision, and excision of other intraoral soft tissue.

A clinical study has been carried out which compared the laser treatment to a standard treatment for patients with periodontitis. The standard treatment used mechanical scaling and root planing for the root surface as well as soft-tissue curettage. The laser treatment used mechanical scaling and root planing for the root surface, followed by laser debridement of the diseased epithelial layers as well as for any chronically inflamed connective tissue.

The patients were treated with standard treatment, laser treatment, or no-treatment on different quadrants of the mouth which were randomly assigned.

For safety, pulp evaluations and tooth surface conditions were performed by blinded evaluators. There were no changes observed in the surface condition of any teeth from pre-treatment to post-treatment. There were no differences in pulp condition between the laser treatment and the standard treatment.

For efficacy, clinical indices and microbiological measurements were made. There were significant differences between the treated teeth and the no treatment teeth in several of the indices at one month and three months. The laser treatment and standard treatment showed equivalent results. By six months all treatment differences had disappeared.

The results of the study allow the following conclusions:

There are no new safety risks for this laser procedure. All teeth in the study were healthy out to six months.

The laser treatment is equivalent to other laser soft-tissue removal procedures in the oral cavity.

The laser treatment for the sulcular debridement and bacterial reduction is equivalent to the standard treatment in terms of effectiveness based on both the improvement in clinical indices.[redacted]