

Indications cleared under K010771

Intended Use(s) of the Device:

The **PerioLase Nd:YAG Dental Laser System** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber optic delivery system. The device will be used in the following areas: general and cosmetic dentistry otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery. The following are the oral-pharyngeal indications for use for which the device will be marketed:

- ... Abscess Incision and Drainage
- ... Aphthous Ulcers Treatment
- ... Biopsies Excision and Incision
- ... Crown lengthening
- ... Hemostatic assistance
- ... Fibroma Removal
- ... Frenectomy
- ... Frenotomy
- ... Gingival Incision and Excision
- ... Gingivectomy
- ... Gingivoplasty
- ... Laser curettage (removal of diseased or inflamed soft tissue in the periodontal pocket)
- ... Operculectomy
- ... Sulcular Debridement
- ... Tissue retraction for Impression
- ... Vestibuloplasty.

Additional indications cleared under 510(k) #014272:

- ... Selective Ablation of Enamel (first degree) Caries.
- ... Exposure of unerupted / partially erupted teeth
- ... Implant recovery
- ... Lesion (tumor) removal
- ... Leukoplakia
- ... Pulpotomy
- ... Pulpotomy as adjunct to root canal therapy
- ... Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
- ... Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility