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-pharngeal 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 YRemoval
- 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