FDA 510(k) Premarket Notification

# K072995 TWINWAVE DENTAL LASER, TIDALWAVE 810 DENTAL LASER, TIDALWAVE 980 DENTAL LASER

**CLEARED**

Dec 18, 2007
56 days to decision

K072995 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072995/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Oct 23, 2007 |
| Decision date | Dec 18, 2007 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Lumen Development and Manufacturing, Inc.** |
| Location | Sandy, UT, US |
| Contact | CALVIN D OSTLER |
| 510(k) history | 1 submissions · 1 cleared · 2007-2007 |