FDA 510(k) Premarket Notification

# K082039 SYNCHRO HP PLATFORM

**CLEARED**

Mar 20, 2009
245 days to decision

K082039 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k082039/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jul 18, 2008 |
| Decision date | Mar 20, 2009 |
| Days to decision | 245 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **El.En Electronic Engineering Spa** |
| Location | Calenzano, IT |
| Contact | ANDREA TOZZI |
| 510(k) history | 27 submissions · 27 cleared · 2007-2023 |