FDA 510(k) Premarket Notification

# K914423 OPTIFIBER

**CLEARED**

Dec 2, 1991
60 days to decision

K914423 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k914423/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Oct 3, 1991 |
| Decision date | Dec 2, 1991 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Minimal Invasive Therapy and Diagnostics, Inc.** |
| Location | Washington, DC, US |
| Contact | PATRICIA B SHRADER |
| 510(k) history | 1 submissions · 1 cleared · 1991-1991 |