FDA 510(k) Premarket Notification

# K912522 OMNIVIEW(TM) OPHTHALMIC FIBERENDO W/NEEDLEHOLDER

**CLEARED**

Jul 25, 1991
64 days to decision

K912522 · Product code: **EQH** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k912522/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Source, Carrier, Fiberoptic Light (EQH) |
| Date received | May 22, 1991 |
| Decision date | Jul 25, 1991 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Summit Technology, Inc.** |
| Location | Waltham, MA, US |
| Contact | KIMBERLEY DONEY |
| 510(k) history | 5 submissions · 5 cleared · 1990-1998 |