FDA 510(k) Premarket Notification

# K973200 CARIES STAIN

**CLEARED**

Nov 6, 1997
72 days to decision

K973200 · Product code: **LFC** · Dental
Source: https://www.510kdatabase.net/k973200/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Caries Detection (LFC) |
| Date received | Aug 26, 1997 |
| Decision date | Nov 6, 1997 |
| Days to decision | 72 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Parkell, Inc.** |
| Location | Mchenry, IL, US |
| Contact | NELSON J GENDUSA |
| 510(k) history | 53 submissions · 53 cleared · 1976-2025 |