FDA 510(k) Premarket Notification

# K812321 HYDROXI-FLEX IMPLANT

**CLEARED**

Oct 29, 1981
73 days to decision

K812321 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k812321/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Aug 17, 1981 |
| Decision date | Oct 29, 1981 |
| Days to decision | 73 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Impladent** |
| Location | Mchenry, IL, US |
| 510(k) history | 5 submissions · 4 cleared · 1980-1995 |