FDA 510(k) Premarket Notification

# K791923 SCLERAL POWDER

**CLEARED**

Jan 10, 1980
106 days to decision

K791923 · Product code: **HQH** · Ophthalmic
Source: https://www.510kdatabase.net/k791923/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Eye, Artificial, Non-custom (HQH) |
| Date received | Sep 26, 1979 |
| Decision date | Jan 10, 1980 |
| Days to decision | 106 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Ocularists , Ltd.** |
| Location | Mchenry, IL, US |
| 510(k) history | 1 submissions · 1 cleared · 1980-1980 |