

K892264 ORALCHEK SUPER-SOFT BRUSHJun 14, 1989
70 days to decisionK892264 · Product code: **EFW** · Dental
Source: <https://www.510kdatabase.net/k892264/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Toothbrush, Manual (EFW) |
| Date received | Apr 5, 1989 |
| Decision date | Jun 14, 1989 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Pfizer, Inc. |
| Location | Mchenry, IL, US |
| Contact | DAVID C OPPENHEIMER |
| 510(k) history | 30 submissions · 30 cleared · 1977-2018 |

Pfizer, Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered in Manhattan, New York City. Founded in 1849, Pfizer is one of the oldest pharmaceutical companies in North America. Pfizer's FDA 510(k) regulatory record includes cleared devices from total submissions, spanning 1977 to 2018. The company's device portfolio demonstrates strength in orthopedic devices, including surgical implants and fixation systems. This regulatory activity is now historical, with no clearances recorded in the past five years. The company's cleared device...
