

K802228 BIOLOGICAL INDICATOR - KEMMED & BIOSUREDec 9, 1980
90 days to decisionK802228 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k802228/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Sep 10, 1980 |
| Decision date | Dec 9, 1980 |
| Days to decision | 90 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kem Medical Products Corp. |
| Location | Mchenry, IL, US |
| 510(k) history | 3 submissions · 3 cleared · 1980-2019 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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