

K854631 ASSERT EO BIOLOGICAL TEST PACKMay 27, 1986
190 days to decisionK854631 · Product code: **FRC** · General Hospital
Source: <https://www.510kdatabase.net/k854631/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Nov 18, 1985 |
| Decision date | May 27, 1986 |
| Days to decision | 190 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Surgicot, Inc. |
| Location | Mchenry, IL, US |
| Contact | JAMES R BROWN |
| 510(k) history | 19 submissions · 19 cleared · 1977-1997 |

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