

K771644 FRAGMATOME MODEL 820Sep 26, 1977
28 days to decisionK771644 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k771644/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Phacofragmentation (HQC) |
| Date received | Aug 29, 1977 |
| Decision date | Sep 26, 1977 |
| Days to decision | 28 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Berkeley Bio-Engineering |
| Location | Mchenry, IL, US |
| 510(k) history | 4 submissions · 4 cleared · 1977-1979 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k771644/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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