

**K832889 AMYLASE**Nov 25, 1983  
95 days to decisionK832889 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k832889/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catalytic Methods, Amylase (JFJ)   |
| Date received         | Aug 22, 1983                       |
| Decision date         | Nov 25, 1983                       |
| Days to decision      | 95 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Pointe Scientific, Inc.,</b>         |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 74 submissions · 74 cleared · 1981-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k832889/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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