

**K931105 PROCHECK(TM) BLIND PERFORMANCE SPECIMENS**Apr 21, 1993  
49 days to decisionK931105 · Product code: **DIF** · Toxicology  
Source: <https://www.510kdatabase.net/k931105/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Mar 3, 1993
Decision date	Apr 21, 1993
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Dynagen, Inc.</b>
Location	Cambridge, MA, US
Contact	PETER J MIONE
510(k) history	6 submissions · 6 cleared · 1992-1996

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931105/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026