

**K880388 T3 SEROZYME ENZYMEIMMUNOASSAY KIT, MAG  
SOLID PHASE**Mar 3, 1988  
35 days to decisionK880388 · Product code: **CDP** · Chemistry  
Source: <https://www.510kdatabase.net/k880388/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Jan 28, 1988
Decision date	Mar 3, 1988
Days to decision	35 days
Third-party review	No

**APPLICANT**

---

Company	<b>Serono Diagnostics, Inc.</b>
Location	Walker, MI, US
Contact	PHILIP M FANTASIA
510(k) history	25 submissions · 25 cleared · 1984-1996

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880388/>; 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 June 28, 2026