

**K891605 COAT-A-COUNT(TM) FENTANYL (TKFN1)**Sep 28, 1989  
192 days to decisionK891605 · Product code: **DJG** · Chemistry  
Source: <https://www.510kdatabase.net/k891605/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 20, 1989
Decision date	Sep 28, 1989
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

---

Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	B ASARCH,PHD
510(k) history	321 submissions · 321 cleared · 1976-2006

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891605/> Data sourced from FDA 510(k) public records (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. - Generated June 21, 2026