

K893976 COAT-A-COUNT (TM) FSH IRMAAug 17, 1989
76 days to decisionK893976 · Product code: **CGJ** · Microbiology
Source: <https://www.510kdatabase.net/k893976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Jun 2, 1989
Decision date	Aug 17, 1989
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	KENNETH ASARCH
510(k) history	321 submissions · 321 cleared · 1976-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893976/>; 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