

K922346 FEMALE URINE SAMPLING DEVICEAug 14, 1992
87 days to decisionK922346 · Product code: **FCN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k922346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Drainage Collection Kit, For Indwelling Catheter (FCN)
Date received	May 19, 1992
Decision date	Aug 14, 1992
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mentor Corp.
Location	Mchenry, IL, US
Contact	BYRON H WICKETT
510(k) history	61 submissions · 61 cleared · 1977-2013

Mentor Corp. is a surgical aesthetics and medical device company based in McHenry, US. Now part of Johnson & Johnson MedTech, the brand supplies products to plastic surgeons and specialists worldwide. Mentor has received FDA 510(k) clearances from total submissions since its first clearance in 1977. The company's regulatory record spans General & Plastic Surgery, Gastroenterology & Urology, Obstetrics & Gynecology, and Radiology device categories. The latest clearance was recorded in 2013, reflecting the company's historical significance in surgical device innovation. Men...

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