

K780848 PORTABLE CLOSED WOUND SUCTION EVACUATORAug 23, 1978
92 days to decisionK780848 · Product code: **GCY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k780848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Suction, Single Patient Use, Portable, Nonpowered (GCY)
Date received	May 23, 1978
Decision date	Aug 23, 1978
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Biomet, Inc.
Location	McHenry, IL, US
Website	http://www.biomet.com/
510(k) history	441 submissions · 419 cleared · 1978-2026

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...
