

K132386 TOTALSHIELD SURGICAL HELMET SYSTEMDec 23, 2013
144 days to decisionK132386 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k132386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 1, 2013
Decision date	Dec 23, 2013
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	ALLISON SCOTT, RAC
Website	https://www.zimmerbiomet.com
510(k) history	374 submissions · 353 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...
