

K192194 TotalShield II Surgical Helmet SystemOct 15, 2019
63 days to decisionK192194 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k192194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gown, Surgical (FYA)
Date received	Aug 13, 2019
Decision date	Oct 15, 2019
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zimmer Surgical, Inc.
Location	Dover, OH, US
Contact	Abigail Miller
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	R&Q Solutions
Contact	Michael Wolford

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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