

K190894 TOTIM Patient Cushion Immobilization SystemApr 30, 2019
25 days to decisionK190894 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k190894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 5, 2019
Decision date	Apr 30, 2019
Days to decision	25 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Essebi Medical Srl
Location	Faetano, SM
Contact	Pietro Sordina
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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