

K191174 Mercy babyTAPEOct 10, 2019
162 days to decisionK191174 · Product code: **PIR** · General Hospital
Source: <https://www.510kdatabase.net/k191174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mercy Tape 2d And 3d Models (PIR)
Date received	May 1, 2019
Decision date	Oct 10, 2019
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Children&apos;S Mercy Hospital
Location	Kansas City, MO, US
Contact	Susan Abdel-Rahman
510(k) history	2 submissions · 2 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	The Emmes Company, LLC
Contact	Susan Abdel-Rahman, Pharmd.

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191174/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026