

K040044 HEEL SNUGLER, MODEL 99047Jan 27, 2004
15 days to decisionK040044 · Product code: **MPO** · Physical MedicineSource: <https://www.510kdatabase.net/k040044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infant Heel Warmer (chemical Heat Pack) (MPO)
Date received	Jan 12, 2004
Decision date	Jan 27, 2004
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	ZITA A YURKO
Website	https://www.respironics.com
510(k) history	172 submissions · 168 cleared · 1977-2024

Respironics, Inc. is an American medical supply company owned by Philips. It specializes in products that improve respiratory functions and is based in Monroeville, Pennsylvania. The company maintains a strong FDA 510(k) regulatory record spanning from 1977 to 2024. Respironics has received FDA 510(k) clearances from total submissions. The dominant focus is Anesthesiology devices, which represent approximately 90% of all submissions. The latest clearance in 2024 reflects continued regulatory activity. Recent cleared devices include masks, ventilators, and sleep therapy sy...
