

K133428 MEDIKRO NANO, MEDIKRO PRIMO AND MEDIKRO PROMay 21, 2014
194 days to decisionK133428 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k133428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Nov 8, 2013
Decision date	May 21, 2014
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medikro OY
Location	Kuopio, FI
Contact	MIKKO ELORANTA
510(k) history	2 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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