

K053430 TONO-PEN AVIA TONOMETER AND OCU-SHILED TIP COVERMar 3, 2006
84 days to decisionK053430 · Product code: **HKY** · Ophthalmic
Source: <https://www.510kdatabase.net/k053430/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	Dec 9, 2005
Decision date	Mar 3, 2006
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Xomed, Inc.
Location	Jacksonville, FL, US
Contact	PENNY LAYMAN
Website	https://www.medtronic.com
510(k) history	37 submissions · 37 cleared · 2001-2026

Medtronic Xomed, Inc. is a medical device manufacturer based in Jacksonville, US. The company specializes in ear, nose, and throat surgical devices and related technologies. Medtronic Xomed has maintained a strong FDA 510(k) regulatory record since 2001. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. The latest clearance was granted in 2026, demonstrating continued active development and market presence in specialized surgical instrumentation. The company's cleared device portfolio focuses primarily on ear, nose, and thr...