

K943939 NON-CONTACT TONOMETER T-2May 12, 1995
273 days to decisionK943939 · Product code: **HKX** · Ophthalmic
Source: <https://www.510kdatabase.net/k943939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Ac-powered (HKX)
Date received	Aug 12, 1994
Decision date	May 12, 1995
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Canon, Inc.
Location	Ohta-Ku, Tokyo, Japan, JP
Contact	H UCHII
Website	http://www.canon.it/
510(k) history	43 submissions · 43 cleared · 1994-2026

Canon, Inc. is a Japanese multinational corporation headquartered in Aomori, Tokyo, specializing in optical, imaging, and industrial products including lenses, cameras, scanners, and semiconductor manufacturing equipment. Canon has received FDA 510(k) clearances from total submissions since 1994. The company's regulatory focus centers on Radiology devices, which represent 74% of submissions. The latest clearance was in 2024, demonstrating continued active engagement with FDA regulatory pathways. Canon's cleared device portfolio includes digital radiography systems and ophth...
