

K183448 NewTom 5G XLMar 8, 2019
86 days to decisionK183448 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k183448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 12, 2018
Decision date	Mar 8, 2019
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	Elena Arcangeli
Website	https://www.cefla.com
510(k) history	20 submissions · 20 cleared · 2008-2026

Cefla S.C. is a diversified industrial group based in Imola, Italy. The company operates through multiple business units, including a dedicated Medical Equipment division that develops dental and diagnostic imaging devices. Cefla has maintained a strong FDA 510(k) regulatory record since 2008. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Its cleared devices span radiology and dental categories, including cone beam computed tomography (CBCT) systems, dental micromotors, and apex locators. The latest clearance was grante...
