

K081088 MYRAY SKYVIEWNov 6, 2008
204 days to decisionK081088 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k081088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Apr 16, 2008
Decision date	Nov 6, 2008
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	BERTHOIN CLAUDE
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...
