

K122198 6.00MM X 6.00MM MACRO EXTERNAL IMPLANT SYSTEM

Apr 5, 2013
255 days to decision

K122198 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k122198/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 24, 2012
Decision date	Apr 5, 2013
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oco Biomedical
Location	Sterling, VA, US
Contact	JACK BLOOM
510(k) history	4 submissions · 4 cleared · 2008-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k122198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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