

OVERJET'S 510(K) FDA CLEARANCES

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FDA CLEARANCE	DESCRIPTION	CLINICAL STUDY DATA
Overjet Caries Assist <u>K222746</u>	Outline and color highlight areas of decay on dental radiographs.	Dentists missed 40% less areas of decay when using Overjet Caries Assist, than without. In the reader study, 100% of dentists detected more decay when using Overjet.
Overjet Dental Assist <u>K210187</u>	Highlight precise bone levels with measurements on dental radiographs	Overjet Dental Assist was able to measure bone levels accurately within 0.35mm or less on bitewing and periapical radiographs, and with 99% as sensitive in detecting bone levels on bitewing (horizontal) radiographs, compared to expert dentists.
Overjet Charting Assist <u>K241684</u>	Highlight and outline: whole tooth, wisdom tooth, enamel, dentin, filling, crown, implant, root canals, and detect/display tooth numbering	Existing restorations were detected with 90% sensitivity, dental tooth anatomy with 95% sensitivity, and tooth numbering with 99% accuracy when compared to a consensus from 12 expert dentists. Segmentation (outlining) of anatomy / restorations was roughly 85-90% as similar (DICE) when compared to a consensus of 12 expert dentists.
Overjet Periapical Radiolucency Assist <u>K231678</u>	Outline and color highlight areas of periapical radiolucency on dental radiographs.	100% of dentists who participated in a clinical study improved in detecting periapical radiolucency on



		images compared to unassisted. Utilizing Overjet's AI, dentists achieved a 63% improvement in detecting previously missed periapical radiolucency.
Overjet Pediatric Caries Assist <u>K233738</u>	Outline and color highlight areas of caries on dental radiographs.	100% of dentists who participated in a clinical study improved in detecting caries on teeth compared to unassisted. Utilizing Overjet's AI, dentists achieved a 57% improvement in detecting previously missed decay.
Overjet Calculus Assist <u>K220928</u>	Highlighting calculus on dental radiographs.	100% of dentists participating in the study improved in detecting calculus when using Overjet than without. Utilizing Overjet, dentists achieved an 43.5% and 45.4% improvement, respectively, in detecting previously missed calculus on BW and PA radiographs.
Overjet Image Enhancement <u>K241681</u>	Uses AI to remove noise and enhance blurry images without losing clinical detail.	Overjet Image Enhancement Assist improves image quality in a process that takes only seconds. In a study of clinical functionality, dentists rated Overjet's enhanced images as approximately 25% higher quality compared to non-enhanced images.