

OVERJET'S 510(K) FDA CLEARANCES

To access Overjet's public 510(k) Summary, please click on the corresponding numbers.

| FDA CLEARANCE | DESCRIPTION | CLINICAL STUDY DATA |
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| Overjet Caries Assist K222746 | 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 K210187 | 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 K241684 | 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 K231678 | 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 |



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| | | images compared to unassisted. Utilizing Overjet's AI, dentists achieved a 63% improvement in detecting previously missed periapical radiolucency. |
| Overjet Pediatric Caries Assist K233738 | 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 K220928 | 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 K241681 | 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. |