FDA Alert - Labs not permitted to use CAD/CAM for in-house milling of most abutments

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When FDA began studying the use of CAD/CAM in dental laboratory technology, the FDA's initial focus was on angulation and the implant/abutment interface. FDA ultimately made clear statements that anyone making the implant/abutment interface is a "manufacturer" as such must obtain 510(k) clearance to do so.

That still did not answer the questions about the "tooth end" of the abutment, the abutment collar/post. Sometime later FDA ultimately stated a dental laboratory may mill the collar/post as long as the dental laboratory follows the manufacturer's FDA cleared instructions.

Now, nearly two years later, there is still only one manufacturer that has obtained FDA clearance for their in-house CAD/CAM milling instructions for their abutment collar/post. FDA's recent communications have alerted us to what this means for dental laboratories:

- With the exception of the abutments of the one manufacturer who has FDA cleared instructions*, dental laboratories may not CAD/CAM mill the abutment collar/post including the Ti-Base type "abutment blanks"

- Abutment blanks may only be hand-milled.

Sirona CAD/CAM System (K111421)

Currently FDA enforcement efforts seem to primarily consist of sending compliance letters to manufacturers as their website marketing is brought to FDA's attention.

NADL monitors FDA regulatory activity on an ongoing basis. As a service to our membership; we strive to keep NADL Members informed on current regulatory developments. NADL Members are encouraged to contact the NADL office by email at nadl@nadl.org or by phone at (800) 950-1150 as a resource for assistance with your regulatory questions.