

by Eric Thorn, Esq.

FDA Sharpens Focus on Implant Abutments

- *NADL was recently requested by an industry trade publication to peer review the contents of a pending article and advertising that made claims on the milling of CAD/CAM abutments. As part of NADL's due diligence, the association reached out to FDA to confirm the actual FDA positions.*
- *Part of NADL's mission is to inform our members on issues of regulatory compliance. As a service to our members, we are sharing FDA's statements.*
- *This information is not new but is and has been FDA's position on the milling of implants within the laboratory setting.*
- *The information contained in this article is taken directly from FDA's written communications to manufacturers, milling centers and NADL.*

As the use of implants continues to grow, manufacturers have been asking FDA about the applicable FDA requirements and whether a dental laboratory may use a CAD/CAM system to create or modify an implant abutment or the abutment collar/post in-house without obtaining 510(k) premarket clearance. Over the past several years FDA has taken a closer look at labs' and manufacturers' use of CAD/CAM relative to abutments. This article describes briefly the evolution of what FDA has communicated on this topic, where we are now, and what this means in practical terms for dental laboratories and abutment manufacturers.

IMPLANT/ABUTMENT INTERFACE – 510(K) CLEARANCE REQUIRED

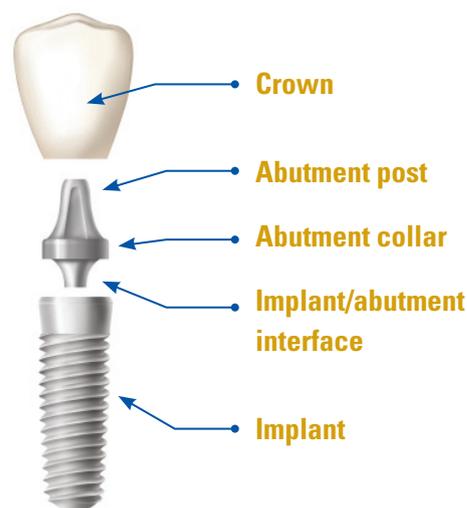
The FDA's initial focus was on the implant/abutment interface. Ultimately FDA made clear statements that anyone making the implant/abutment interface is no longer a "dental laboratory" from a regulatory perspective, but rather is a "manufacturer" of a class II medical device and per the applicable regulations, must obtain 510(k) clearance to do so. Please note that it is in this regulatory context that the terms, "laboratory" and "manufacturer" are used in the discussion that follows.

WHAT ABOUT THE ABUTMENT COLLAR/POST

This still left some questions about the other end of the abutment, the abutment collar/post. In meetings with industry groups going back to at least March of 2014, FDA's direction had been that as long as the dental laboratory follows the manufacturer's specific instructions, and the manufacturer's instructions have been 510(k) cleared by the FDA, a dental laboratory may mill the collar/post for a specific patient pursuant to a dentist's prescription without the lab having to obtain a separate 510(k) clearance.

FDA also pointed out; at that time they were only aware of one manufacturer whose instructions for dental lab in-house CAD/CAM milling of their abutment collar/post had been FDA cleared. Initially, many believed that it was just a matter of time before other manufacturers obtained a similar 510(k) clearance of their instructions for dental lab in-house CAD/CAM milling for their abutment collar/post. However, to date this has

Photo courtesy of the American Academy of Implant Dentistry



not materialized and we are only aware of one other Ti-base/hybrid abutment manufacturer that appears to have 510(k) clearance of their instructions for in-house CAD/CAM milling of the abutment collar/post by a dental lab.

During the course of this past year FDA has provided greater detail on various practical situations. A closer look at FDA's clearance requirements for dental lab in-house abutment milling instructions will help readers to understand some of the challenges and why there are still only one or two manufacturers that have been able to obtain 510(k) clearance of their instructions.

FDA CLEARANCE OF INSTRUCTIONS FOR DENTAL LAB IN-HOUSE MILLING – THE CHALLENGE

Endosseous dental implant abutments are regulated by the FDA as Class II medical devices and as such are subject to FDA regulations, including 21 CFR 820. As abutment manufacturers desirous of obtaining FDA clearance of their instructions for dental lab in-house milling approached FDA, they discovered that their instructions must be cleared for a specific combination of design software and specific manufacturer's CAD/CAM system.

So if an abutment manufacturer obtained FDA clearance for instructions for dental lab in-house collar/post milling

using WOW software and an ABC CAM system, a lab that was using WOW software and an XYZ CAM system would not be able to mill the collar/post unless the abutment manufacturer separately documents the change, validates the new device system, and potentially obtains an additional clearance of instructions for that combination of system, material and design parameters. This may help to explain why only one or two Ti-base/hybrid abutment manufacturers have obtained FDA clearance for their dental lab in-house CAD/CAM milling instructions.

Further, it is not sufficient for a supplier to provide instructions for the specific software and CAD/CAM equipment to use and instructions detailing the FDA cleared design parameters that should not be exceeded. Rather, to obtain clearance of their “instructions” for dental lab in-house milling of an abutment collar/post, the manufacturer must show FDA that the instructed specific combination of system, material, and software includes a built-in “hard stop” so that it is not possible for the lab to exceed the abutment manufacturer’s 510(k) cleared design parameters.

If we use an automobile as an analogy, an automobile manufacturer would not be able to obtain clearance for driver instructions that simply instruct the driver not to operate the automobile above the cleared range of speeds, even if there were a visual or audible warning. Rather, to obtain FDA clearance of its driver “instructions”, the manufacturer would be required to design the automobile so that it is not possible for the driver to operate the automobile in excess of the cleared maximum speed.

FDA’s requirement that “instructions” be cleared really means that a manufacturer’s system must incorporate hard stops so that it is not possible for a lab to exceed cleared design parameters. Perhaps this coupled with requiring hard stops be incorporated into a specific combination of system, material, and design parameters is why manufacturers have so far found it daunting or not cost effective to 510(k) clear their instructions for dental laboratory in-house CAD/CAM milling.

IMPACT ON DENTAL LABS

In-house Milling

FDA was only aware of one or two Ti-base/hybrid abutment manufacturers whose instructions for dental lab in-house CAD/CAM milling of the abutment collar/post have been cleared by FDA. FDA has not identified any other abutment manufacturers who have been able to clear instructions for dental lab in-house CAD/CAM milling. However, milling of the collar/post may be done by the “manufacturer”/510(k) holder or by a lab that meets the requirements to become an FDA registered contract manufacturer of a 510(k) cleared abutment.

In-house Design by Dental Labs

There are software systems that have been cleared for dental lab in-house design of patient specific modifications to the abutment collar/post which are then milled at a manufacturing facility under the control of the abutment manufacturer who holds the 510(k) for that abutment.

Abutment Blanks – Cleared for Hand Milling Only

While this does not apply to a “lab” that is registered with the FDA as a manufacturer of an abutment with 510(k) clearance that uses a blank as part of its cleared process, it is important to note that FDA states that there are currently no abutment blanks that have been FDA cleared for in-house CAD/CAM milling by a non 510(k) holder dental laboratory. For dental laboratories, FDA states that single piece abutment blanks with a pre-milled connection platform and a large cylinder for formation of the collar and post are cleared for hand milling only.

One odd result of this is that a lab can mill an abutment blank by hand but cannot use their best tools (CAD/CAM milling) to achieve what would be the same, or likely a better result for the patient.

IMPACT ON ABUTMENT MANUFACTURERS

Abutment Manufacturers

While manufacturers of 510(k) cleared abutments may mill their own abutment

collar/post modifications from a dental lab’s in-house patient specific design, if they want labs to be able to CAD/CAM mill the collar/post in-house, their in-house milling instructions would need to be 510(k) cleared. To accomplish this, the manufacturer would need to work with software and/or a CAD/CAM partner(s) to develop hard stops that prevent a lab from milling outside of the manufacturer’s 510(k) cleared abutment design parameters for angulation, etc.

Blank Manufacturers

Unless milled by a manufacturer of a 510(k) cleared abutment as part of their cleared process, FDA states that blanks are cleared for dental lab hand milling only. Accordingly, websites must not state that the blanks can be CAD/CAM milled in-house by a dental lab that is not also a “manufacturer” of a 510(k) cleared abutment since FDA states that no blanks have been FDA cleared for in-house milling by a dental laboratory.

FDA ENFORCEMENT

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

As a service to our membership we strive to keep NADL members informed on current regulatory developments. NADL members may to contact the NADL office as a resource for assistance with regulatory questions. **JDT**

All rights reserved. Reprinting permitted by written permission of NADL only. Inquiries for use should be directed to: Editorial Staff, National Association of Dental Laboratories at (800) 950-1150

Nothing in this article is intended as, nor should it be construed as or relied upon as legal advice. Please consult your legal advisor or a qualified compliance consulting professional to determine any applicability to your individual business activities.