Grow Your Laboratory with the Understanding of the FDA Requirements

Grow your laboratory with a clear strategy to comply with the FDA and incorporate all the services that are now available to offer your clients without fear of the FDA. Offer your dentist client a teamwork treatment plan with surgical guides, immediate temporaries and mill the Ti bar or the Ti custom abutments for that case and more to do while staying within compliance of the FDA. The critical factor here is to know what the FDA requirements are and stay within them. Get to know the FDA's position.

The dental laboratory industry continues to incorporate CAD/CAM automated manufacturing while the FDA is making clear their position on some regulatory requirements for these laboratory manufacturing processes. Over recent years, the FDA has evaluated the manufacturing processes for CAD/CAM restorations and is bringing forward some changes, with probably more requirements to come.

The FDA's Product Classifications are giving us light on manufacturing requirements. Here are examples of these Product Codes, some changes and how they affect the dental labs production:

1. **Additively Manufactured, Preformed Resin Denture Tooth**

The product classification for 3D printed denture teeth for the fabrication of preformed resin denture teeth for use in a denture base (Product Code PZY) is very straight forward. The product is a Class 2 device, 510(k) exempt but requires to be produced under the Quality System (QS) Regulation. Good news for dental laboratories 3D printing dentures. So, in laymen's terms, the only requirements are that dental labs must use 510(k) cleared resin to print the denture teeth and operate under a Quality Management System.

2. Accessories, Implant, Dental, Endosseous

This product classification includes Surgical Guides for dental implants and this modification will definitely have an impact on printed or milled surgical guides. The FDA added a "Note" to the Product Classification to the Product Code NDP stating that a dental laboratory or a surgical guide service provider must register their establishment and operate under a Quality Management System. This is the modification that occurred without "written guidance" for the industry to prepare for the change. In communications the FDA Division of Industry and Consumer Education (DICE) and from the Imports and Registration and Listing Team specifically

directed us that the manufacturer of a CAD/CAM Class 1 surgical guide would be regulated as a device manufacturer and required to comply with the FDA requirements, including having to register their establishment, list their product, and would need to follow the Quality System (QS) Regulation.

3. Abutment, Implant, Dental, Endosseous

The product classification for dental implant abutments have direct modifications to the 510(k) requirements for the Ti Blanks and Ti Bases. Both of these implant abutments, Product Code NHA, fall into the same FDA requirements for the 510(k) Holders/Manufacturers of implant abutments. These 510(k)s have a unique statement added to their IFUs. The manufactures of the devices, dental laboratory or milling centers must be a "Validated Milling Center". When we asked the FDA to explain their requirements for these Validated Milling Centers, they provided the following information:

"Like a contract manufacturer of any Class II medical device, a validated milling center is responsible for registration/listing of the facility and devices produced as well as implementation of manufacturing procedures in line with Quality System Regulations".

3 Methods used by the FDA to Add and Modify Requirements Regarding CAD/CAM Restorations

Above are 3 different methods used by the FDA to deliver information of how they modified requirements and regulations.

1. The FDA introduced the new Product Code PZY for the Additively Manufactured, Preformed Resin Denture Tooth.

2. They added the "note" to an existing Product Code NDP Accessories, Implant, Dental, Endosseous involving the implant surgical guides.

3. Add a requirement for CAD/CAM manufactured NHA abutments IFU in their 510(k) Clearances to use only "Validated Milling Centers" for the manufacturing of the Ti Blank and Ti Base implant supported restorations.

We are seeing the "establishment exemption" removed from more CAD/CAM procedures in dental laboratories. Those labs still using the traditional analog handmade methods will always have that exemption. But as an industry, the move to automated manufacturing will require more dental laboratories to register with the FDA and be open to the FDA audit.

This very event, the audit, that so many dental lab owners fear, is misguided. The FDA does not want to shut down dental laboratories. The FDA recognizes the critical role that these medical device manufactures play in each patient's oral health care.

With that, our experience with the FDA during over 8 audits, has demonstrated that the FDA is looking for ways to help you improve your quality system. As stated by Lab owner Kevin Crane

in his May JDT article, “Whose Afraid of the Bid Bad Wolf” demonstrated the FDA investigator was looking to help them understand and improve a Quality System. It is only those labs that are in gross negligence or are simply operating outside the law will have the FDA act to interrupt their laboratory production until they are operating safe and producing a consistent quality device. This situation is rare and has just happened with production stoppage due to illegal activity but for a lab to become and remain FDA compliant is not that difficult or overly burdensome for CAD/CAM labs. Being FDA compliant is by far less intrusive than being compliant with the outdated DAMAS quality system.

Instead of fearing the FDA, accept the fact that they are here and not going away. By getting FDA compliant, a dental laboratory can bring many manufacturing procedures inhouse, stop outsourcing gaining higher profit margins on the medical devices you provide directly to your dentist clients. There has been misinformation used to instill fear that unnecessarily has kept you staying in the shadows, keeping you from building a bigger and better lab. Build a true CAD/CAM production business and increase revenues by offering a complete line of dental restorations while touting and promoting your FDA compliance.

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