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Crucial Awareness:
FDA, Orthodontic Appliances and the Labs that Make Them

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Over the last couple of years, a disturbing pattern has emerged when it comes to the Food and Drug Administration's focus on orthodontic labs and the appliances that they manufacture.

The FDA traditionally has had a hands-off approach to dental laboratories that make "patient specific" or "patient matched" dental devices that are not classified by FDA. This meant that if a dental laboratory did not manufacture a classified device, such as sleep apnea/anti-snoring devices, sequential aligners, or milled customized implant abutments, it would not have to register as a medical device manufacturer. The majority of dental laboratories thus were not on FDA's radar for inspection.

The basis for this "exemption" is found in The Code of Federal Regulations, Title 21, Subchapter H, Part 807, Subpart D, § 807.65(i) which stated, "Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device."

In order to register with FDA, there must be a product code assigned by FDA to the product. As stated in the exemption, dental labs can manufacture devices without registration if they use materials that have been registered and listed by the manufacturer, the "previously manufactured device" noted in § 807.65(i). There are product codes for all of the materials that dental labs use to manufacture their products. There are no product codes for domestically manufactured prosthetic devices, such as crowns, bridges, partial and full dentures. There are product codes for classified devices such as sleep/anti-snoring devices, sequential aligners, customized implant abutments, and a few others.

This brings us to the orthodontic world. While the fixed and removable devices previously mentioned are restoring a patient's oral function and aesthetics by replacing damaged or missing teeth, orthodontic appliances are designed to move, align, or straighten existing teeth and jaw structures. Many of these orthodontic devices have been around for years and were developed by practitioners, so many of them are named after the developer of the appliance, such as the Hawley retainer, Herbst appliance, Haas appliance, et al.

Why is this history lesson relevant to the topic of this article — FDA and its focus on ortho labs and products?

In recent years some FDA inspectors in orthodontic laboratories have made comments that all orthodontic labs should be registered with FDA and

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that the majority of the appliances manufactured by the lab should be listed in those registrations. This is based upon the existence of a device classification regulation number in the Code of Federal Regulations, § 872.5410 Orthodontic appliance and accessories. "(a) Identification. An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire."

There are 11 different product codes under this regulation for the accessories listed in the regulation. These are some of the materials used in the orthodontic appliances. These codes make everything listed in the regulation a Class I medical device, exempt from a 510(k) submission to FDA.

The manufacturers, whether domestic or foreign, of the accessories such as the bands, brackets, springs, wires, and expansion screws noted in the regulation do have to register and list.

Traditionally, orthodontic labs have not registered and listed the appliances with FDA, based upon the same exemption, § 807.65(i), mentioned earlier in this article. They are making devices based upon the prescription of a licensed practitioner and not marketing the devices to consumers. There are a number of laboratories that have registered and listed under this product code, many of them foreign labs that must register to export to the U.S. and labs in the U.S. that import the appliances. A very few labs have registered and listed their appliances. Registration and listing is an annual fee that has increased substantially over the last few years to the current 2026 fee of $11,423.

Registered laboratories will most likely be inspected by FDA at some point in time. The inspection primarily focuses on the required Quality Management System but also may discover issues with registration and listing. That has been the case in some of the recent inspections where investigators have noted that appliances needed to be listed. FDA's authority is not limited to inspections of registered establishments, they may inspect any dental laboratory if they suspect noncompliance with registration and listing issues.

Recently FDA has issued letters of inquiry to some orthodontic labs based upon review of marketing materials on lab websites. RPEs (Rapid Palatal Expander) were the appliances that drew FDA's scrutiny. RPEs are used to widen a narrow upper jaw to aid in proper alignment of the patient's teeth. It does this through applying gradual pressure using an adjustable screw mechanism to move both halves of the upper jaw. There are several variations of the appliance. FDA was paying particular attention to the Miniscrew — Assisted RPE (MARPE). This RPE is attached to the palate using the miniscrews.

Recent inspections and inquiry letters asked the labs to respond as to why these types of appliances were not registered or listed. Looking at the function of the appliance, it may seem to meet the description of a medical device by treating a condition rather than just restoring function as crown and bridge or dentures do. The RPE can also be used to treat sleep apnea, which definitely makes it a classified medical device.

Other devices, such as splints and guards, have received FDA scrutiny during inspections relative to their function as well.

Is there a paradigm shift in FDA's approach to orthodontic appliances or are these inspection observations and inquiry letters just coincidental blips?

The outcome could have a significant impact on the orthodontic laboratory sector. **JDT**

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About the Author

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