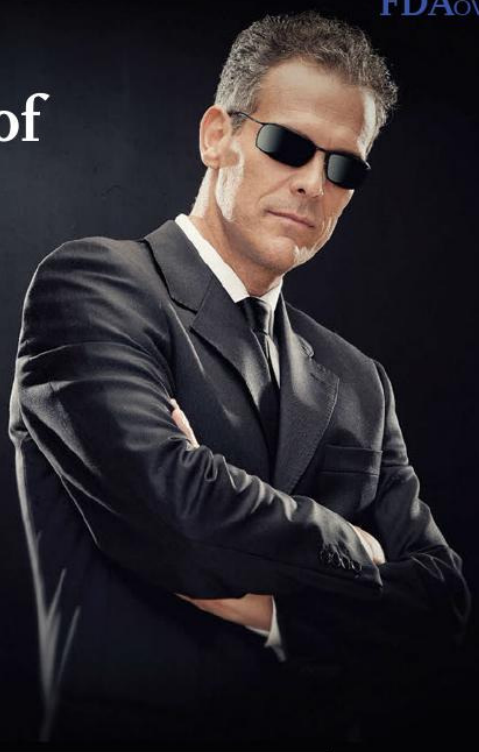
# The Regulatory Side of Oral Sleep Devices

*by Laura Sheppard, CDT, TE*



A dental laboratory technician is rarely seen by the patient, yet is always in the foreground of a successful device. For many years, when lecturing to my contemporaries and newcomers, I often joked that "we are the Men in Black, no one knows we exist".

Up until the 1990's, dental labs and technicians have only been required to comply with the state Dental Practice Acts of the states they conduct business in. And while each state has differing requirements, it is and has always been the responsibility of the technician and the dentist to insure this compliance. But in 1994 the Food and Drug Administration determined that dental devices for obstructive sleep apnea were to be classified as Class II medical devices. This meant that any device carrying the claim of treating a medical disease, had to be registered with the FDA. Those of us that had been making sleep devices for our dental clients were sent into a tail spin, not knowing what the implications would be.

For dental labs, the FDA stepped forward as our new regulatory body to insure patient safety. Any labs manufacturing these devices would have to register and pay annual fees. For inventors, in order to register a device, premarket approval would be required. Section 510(k) of the Food, Drug and Cosmetic Act requires that a Class II medical device owner must notify FDA of their intent to market a medical device at least 90 days in advance. While a notification sounds simple enough, it's the approval process that has evolved into an incredibly laborious and costly venture for all parties. And it's that approval that must be obtained before a device can be registered or manufactured for patient use. The testing and documentation required to earn a 510(k) approval in the best case scenario can actually take from 6-9 months and most often requires the services of a regulatory professional and possibly even chemical laboratory and material testing facilities.

Further historical events have shaped the regulatory oversight that is in force today. In 1997, the FDA established 21 CFR Part 820 as a code to regulate imported dental items. Known as the Quality System Regulation code, it identifies Good Manufacturing Practices (GMP) for manufacturers. Then in 2004, the FDA confirmed to the National Association of Dental Laboratories (NADL), that all labs must comply with the FDA's QSR code and GMP requirements insuring properly labeled and designed dental products for their intended dental procedure. The most common third-party auditable GMP system certification for labs is the DAMAS (Dental Appliance Manufacturing Audit System) or ISO (International Standards Organization) certifications. Finally, you may remember in 2008 we had the "Lead in Crowns" scare, which

**Any device carrying the claim of treating a medical disease has to be registered with the FDA.**

opened up an entirely different realm of issues, but most importantly placed a public spotlight on dental laboratories. No longer the Men in Black, this lead to the FDA's determination and notification that all dental laboratories would now be under their purview and part of their "investigational inventory", and as such would be subject to inspection. Dental labs would now be audited for their GMP's to include complaint systems, lot number tracking for materials, vendor verification systems, recall systems, and much, much more. They also must understand and be able to verify the safety of dental devices, outsourcing requirements, dental technician competency, gray market materials, etc.

Today, many labs are rolling the dice. Some know their dentist-clients are unaware and are counting on the lack of FDA resources to conduct audits. Others are unaware or misinformed. They do not have quality systems in place. They are not registered nor do they follow regulatory requirements. Many dentists do not know these requirements, either. It remains the joint responsibility of the lab and the dentist to insure regulatory compliance for the safety of the patient. The most significant facts and rules that are unknown or overlooked are:

- **U.S. Law:** Unlike our EU counterparts, United States dental lab technicians are not required to have a formal education, specific training or demonstrate core competency. Like 'Diplomat' status, becoming a Certified Dental Technician is a challenging, but voluntary achievement.
- **All State Dental Practice Acts:** A lab may NOT proceed with manufacturing a dental device or restoration without a **signed Rx.** FDA GMP will require you to call the prescribing dentist and ask for a signature. In all my years, it is rare I that I find a dentist that is understanding and not angry at the required 'stop work order'. Inconvenient? Yes. But it's the law. In fact, it's the dentist's own law.
- **All State Dental Practice Acts:** A lab may NOT proceed with manufacturing a dental device unless prescribed by a dentist; not an ENT, medical doctor or surgeon (unless a dental/oral surgeon).
- **Some State Dental Practice Acts:** State requirements vary and may not include any patient safety measures at all. While some states require such things as lab registration in state, full material disclosure on invoices, point of origin disclosure on invoices, jurisprudence testing, a Certified Dental Technician (CDT) on staff, denture/partial or removable appliance identification, etc. And some states do not allow such things as technician shade taking and denturism.
- **FDA:** Even with a dentist's prescription, dental technicians may NOT design or manufacture a device for a dentist (even as a singular patient-specific device) if the prescription states it is for the treatment of obstructive sleep apnea (a Class II device) and it does not already have a 510(k).
  - Lab prescriptions and invoices are subject to FDA audit
- **FDA:** Labs may NOT manufacture a Class II medical device unless they are FDA registered as a Manufacturer or a Contract Manufacturer.

*A practicing dental technician since 1979, **Laura Sheppard** holds an Associate's Degree in Dental Technology and a Bachelor's Degree in Allied Health Teaching. She is certified in Orthodontics, Crown & Bridge and Complete Dentures.*

*Laura owned her own full service dental lab for 7 years then moved to serve Dental Services Group's Davis Laboratory for 22 years. At DSG Davis, she developed their Ortho and Splint and Sleep departments, then served as their Director of Training & Education and Director of Quality & Compliance. In 2012, Laura joined the Microdental Laboratories team where she was Senior Director of Quality, Compliance and Regulatory Affairs. Laura has earned DAMAS certifications, successfully coached over 45 technicians to achieve their national certifications and was instrumental in the invention, patent and 510(k) submission process of several successful proprietary Class II medical device products for both of these laboratory conglomerate companies. Laura has been manufacturing dental sleep devices since 1988 and has been an active participant with the AADSM since 1991. She is now the owner and managing member of Device Masters Dental Laboratory in Traverse City, Michigan, providing devices for dental sleep medicine, TMJ dysfunction and orthodontics.*

*Laura currently serves on the NADL Board of Directors and is the Immediate Past-Chair of the National Board of Certification. Laura lectures for both, the dental practitioner and dental technician communities, and is well published having written numerous articles for JDT, IDT, DPR, DLP, LMT and Sleep Review. In 2011, she was named one of the Top 25 Women in Dentistry by Dental Products Report.*

- Some labs assume that vendors who sell the parts or kits are the liable party for registration. This is not true. If you are not the 510(k) owner and manufacturer, then you are a Contract Manufacturer (approved to manufacture by the owner) and must be registered as such.

- **FDA:** U.S. labs that outsource a Class II medical device to be manufactured in a different domestic facility must be FDA registered as a Repackager/Relabeler.
  - These labs must also disclose the outsourcing to the dentist on the invoice. For an entirely outsourced case, this message may look like "designed and distributed by ABC Lab" (not "manufactured by ABC Lab"). For a portioned case, the message should look like "x part manufactured by ABC lab" and "x part distributed by ABC Lab".
- **FDA:** U.S. labs that outsource a Class II medical device to a non-domestic facility for manufacture and then import directly from the non-domestic facility must be FDA registered as an Initial Importer.
  - **FDA:** These labs must also disclose the outsourcing to the dentist on the invoice, in the same manner as domestic requirements.
  - **CBP:** Customs and Border Protection Act also requires the end user (defined as the dentist not the patient) to have been given notice of the actual address of the manufacturing facility if it is located out of the United States.
- **FDA:** U.S. labs that outsource a Class II medical device to a domestic facility for non-domestic manufacture and then receive from the domestic (exporter) facility must be FDA registered as a Distributor.
  - These labs must also disclose the outsourcing to the dentist on the invoice, in the same manner as domestic requirements.
  - **CBP:** Customs and Border Protection Act also requires the end user (defined as the dentist not the patient) to have been given notice of the actual address of the manufacturing facility if it is located out of the United States.

As a final point in fact, in the United States, healthcare compliance is also required and guaranteed by law. Understanding the existing laws, whether we agree with them or not, is imperative to patient safety. We all know that healthcare should be offered with the best and safest services possible.

We're no longer the Men in Black. Regulatory oversight is here. And they're here to stay. When it comes to designing devices, inventors need to operate within the FDA and 510(k) guidelines, instead of asking a laboratory to manufacture a non-regulated device design. Dental labs should only be manufacturing a licensed device with the contract approval of the inventor or 510(k) owner and they should be registered as a contract-manufacturer. Additionally, all sleep device manufacturing labs need to be FDA registered, outsourcing must be done with full and proper disclosure and materials must be FDA registered and accepted. Ignorance of the law excuses no one. Dentistry, clinicians and laboratories alike, must do their best to become informed and act in accordance to provide the highest level of medical device service for their patients. DSP

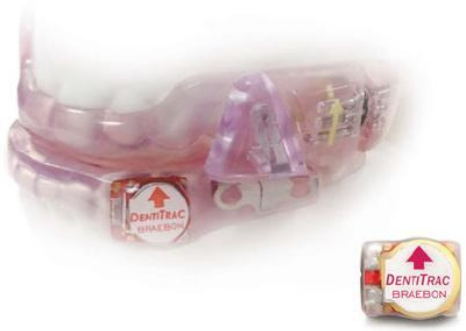
**Understanding the existing laws, whether we agree with them or not, is imperative to patient safety.**

BRAEBON
For Today's Business of Sleep™

It's Here!!

*Wear it. Trac it®. DentiTrac®*

DentiTrac is now available in
the USA for use with select appliances.







For more information
call 888-462-4841 x218

www.braebon.com
@braebon