

NADL

National Association of
Dental Laboratories

Established in 1951

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RE: Docket No. 02D-0011

Documents Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Dear Center for Devices and Radiological Health,

On behalf of the dental laboratory industry, we applaud the Food and Drug Administration's continued efforts to ensure the safety of the public relative to the use of medical devices.

However, the National Association of Dental Laboratories would like to share some comments relative to the draft guidance on Class II Special Controls for Sleep Apnea Devices and its applicability to the dental laboratory setting.

In conjunction with a prescription work authorization from a licensed dentist, dental laboratories prepare sleep apnea devices using upper and lower impressions from the dental patient. These types of dental devices have proven to be reasonably comfortable to wear by the patient; and significantly reduce or eliminate snoring for the patient who has been referred to an appropriate healthcare provider before prescribing the device. Nonetheless, it must be reemphasized that the dental laboratory does not design the prosthesis. This is done at the direction of the dentist's prescription.

There are several treatment methods for sleep apnea, with dental devices being one of several major devices. The manufacture of these devices is a small percentage of the dental laboratory business. If the draft guidance on Class II Special Controls for Sleep Apnea Devices applied to dental laboratories, the additional paperwork associated with such a ruling would place dental laboratories in a position to weigh the costs and benefits of delivering these types of products. We estimate that a good number of laboratories performing this service today would decide to cease offering such services if the guidance were adopted as presented.

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As it is written, the guidance document is written for the manufacturers of kits (the parts and pieces and materials needed to create the device), not labs. The only time a lab would come under the auspices of the guidance document is when they manufacture a device that isn't a kit approved by the FDA.

Currently, any material to be used in the manufacture of a dental prosthesis or treatment device delivered in the U.S. is already subject to FDA guidelines. Dental laboratories are well versed at complying with a myriad of regulatory provisions, including hazardous material and infection control procedures and compliance with MSDS material disclosure forms.

Another area of concern is that the American Dental Association currently does not provide any mandated curriculum for sleep apnea devices for licensed dentists. Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

It is the opinion of NADL that laboratories should only manufacture FDA approved sleep apnea appliances and continue to provide the appropriate information to the prescriber in a voluntary manner.

Finally, it should be noted that a number of such devices are manufactured by offshore dental laboratories, which are not subject to using FDA approved materials.

If you require further information, please feel free to contact our association at 1-800-950-1150.

Sincerely,



Richard Harrell, CDT, President



Elizabeth Curran, CDT, Competency Standards Chair

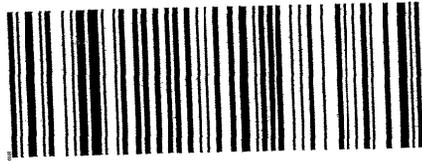
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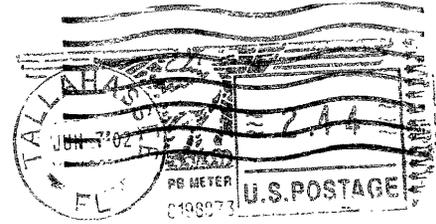
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