



# MYOTRONICS-NOROMED, INC.

Leading in Musculoskeletal Evaluation Technologies For Over 30 Years

September 3, 2002

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Documents Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

**Reference:** 21 CFR 872, Docket #02N-0305  
Dental Devices, Jaw Tracking & Sonography  
Federal Register 08-14-02, 52901-52905

Dear Sir/Madam:

We are writing to comment on the content of the above referenced proposed rule.

We believe that the wording of the proposed rule is confusing and ambiguous. The FDA's intent seems obvious when the language clearly states that a device, otherwise Class I, would become Class II "*when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain.*" (FR p. 52901) (The same statement is made with respect to jaw tracking devices.) FDA intent is further reinforced by the statement on page 52903, paragraph 2, Improper Treatment which states that "*the output of these devices are adjunctive to other diagnostic and therapeutic modalities.*" We do not have a problem with these statements on their face. However, as one reads on in the descriptions of the Class I versus Class II categories, we believe the wording to be very confusing and ambiguous.

To illustrate, the definition of a Class I Sonography dental device is one that "*detects and records sounds made by the temporomandibular joint.*" (FR p.52905). The same device becomes medical Class II if "*the device detects, records, displays and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by means of connection to a personal computer.*" (FR p.52905)

It seems clear, and we would agree, that if a device interprets such information it is making a diagnosis and would properly be a Class II device. In the case of the Sonography device marketed by Myotronics, the manufacturer does not claim that the device makes a diagnosis, only that it provides information that the clinician can use together with other adjunctive devices and his/her training, experience, skills and clinical judgement. However, the ambiguity of the wording could make a computer based measurement device that simply captures, displays and stores basic measurement information Class II even if it does not interpret. It would seem appropriate to clarify that the word interpret means that the claim that it makes a specific diagnosis is what makes the device a Class II device. It should be made clear that meaningful output by itself does not make an otherwise Class I device a Class II device if an otherwise Class I device does not claim to provide by itself a diagnosis.

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Precisely the same ambiguity exists in the wording of the section describing jaw tracking devices.

In summary, we believe the operative word to be interpret, and the wording through the entire publication must be clarified to make it clear that even computer based devices that collect, store and display measurement data used by the clinician are not Class II devices unless the manufacturer claims that it, by itself, makes a diagnosis using such data.

Respectfully,

A handwritten signature in black ink, appearing to read "Fray Adib", with a stylized flourish at the end.

Fray Adib, BSEE, MBA  
President

FA/gw



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