Blade-Form Dental Implants: FDA Reclassification as a Class II Dental Implant Device

The US Food and Drug Administration (FDA) provides guidance on the regulatory controls needed to reasonably assure the public regarding the safety and effectiveness of dental devices. The device regulatory pathways consist of three categories: Class I (general controls), Class II (special controls), and Class III (premarket approval). In January 2013, the FDA proposed reclassifying blade-form endosseous dental implants from a Class III device to a Class II device. The Class III regulatory pathway traditionally consists of extensive preclinical studies and multi-centered double-blinded clinical trials that involve considerable time and expense. The Class II pathway involves a 510k clearance, where the manufacturer's obligation is to demonstrate "substantial equivalence" to an existing Class II cleared device. Traditionally, a 510k clearance involves less time and expense than a premarket approval.

The May 28, 1976, Section 513 amendment of the Food, Drug, and Cosmetic Act (FD&C Act), designated that devices in commercial distribution prior to the enactment of the amendments would be classified based upon a 3 step process. 1) recommendation from an FDA device classification advisory panel, 2) publication of the panel's recommended regulatory designation for comment, and 3) publication of the panel's final designated regulatory pathway. On December 20, 1980, all dental implants (regardless of geometry) were given a Class III designation. Section 513(e) of the FD&C Act was amended on July 9, 2012, to allow for the reclassification of classified preamendment devises by administrative order based upon "new information." New information could be the result of re-evaluating data given the FDA when the device was originally classified, plus information not presented, available, or developed at the time of the original classification (http://www.gpo.gov/fdsys/pkg/FR-2013-01-14/html/2013-00388.htm).

In 1998, the FDA formed a reclassification panel and found sufficient clinical information had been presented to warrant reclassification of root-form implants, implants with special retention features, and temporary implants as Class II devices. Therefore, root-form dental implants would henceforth require the less burdensome 510k regulatory pathway. The panel also stated, "sufficient evidence had not yet been presented to reclassify blade-form endosseous dental implants to Class II."

In 2009, the FDA requested that information for reclassification of blade-form implants be submitted, but only one device manufacturer responded. Unfortunately, the information submitted related to other types of dental implants and was not relevant to the reclassification issue.

On January 14, 2013, the FDA, through its own initiative and based on new information proposed to reclassify the blade-form endosseous dental implant. The FDA requested that comments on this proposal be submitted by April 15, 2013. Two American Academy of Implant Dentistry Fellows/American Board of Oral Implantology Diplomates provided comments and on July 18, 2013, presented before the FDA.[1] Edward Hughes, DDS, and Ralph Roberts, DDS, provided information which assisted the FDA in concluding: 1) The available scientific evidence supports a reasonable assurance of safety and effectiveness for the use of endosseous dental implants (blade-form) for restoration of chewing function; 2) the proposed special controls can be established; and 3) there is not an unreasonable risk of illness or injury for the endosseous dental implants (blade-form) when general and special controls are applied (http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM360930.pdf).

There is current best evidence to support this reclassification of blades. In 1996, Steflik et al[2]

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studied 120 titanium and ceramic root-form and titanium blade implants in 30 dog mandibles. Computerized morphometry data found that titanium implant systems were apposed by more bone than ceramic implant systems. Titanium implants systems (50–65%) were apposed by significantly more bone than the ceramic systems (41–50%). Two-stage titanium implant systems exhibited the highest bone contact length (BCL) percentage, ranging from 58.0% to 65.6%. Two–stage titanium cylindrical implants had significantly higher BCL than the other systems. However, two-stage titanium blade implants also displayed high BCL, ranging from 50% to 58%. At 29 months the difference between the two-stage titanium cylindrical systems and the two-stage blade-form systems diminished. The authors concluded that a two-stage surgery protocol was important for success of the titanium blade-form implants.[2]

In 2002, Proussaefs and Lozada[3] reported the clinical, radiographic, and histologic evaluation of 2 immediately loaded Vitallium blade-form implants recovered from the posterior maxilla of 2 patients after 21 years (no coating) and 13 years (hydoxyapatite coating) of function. Neither implant demonstrated mobility or pathology, and both appeared to have integrated with surrounding bone.[3]

In 1996, Roberts[4] found that plate-form (aka, blade-form) implants had shown a high rate of success over 25 years of service. The design of the blade-form implant contributes to the blade-form's success because applied forces are transferred over a large area of bone.[4]

Root-form design, surface coatings, and surgical instrumentation have evolved since the FDA changed the original Class III root-form implant designation to a Class II 510k regulatory pathway in 1998. Once the regulatory hurdles were reduced, researchers and manufacturers innovated and improved root-form technology. The same will happen with blade-form titanium implants. Hopefully, these advances will be forthcoming following the change in the regulatory pathway. Blade-form implants do provide alternative treatments for atrophic ridges. They reduce the need for bone grafting and multiple surgeries. Patients will benefit from the reduced morbidity and costs associated with bone grafting procedures. Implant dentistry educators, manufacturers, researchers, and clinicians from all disciplines in implant dentistry must now work together to advance blade-form technology. I ask that we not fear this change, but rather embrace it.

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References

1. Hughes ER. Food and Drug Administration: reclassification of blade form dental implants. *J Oral Implantol*. 2013;39:523–524.

2. Steflik DE, Lake FT, Sisk AL, et al. A comparative investigation in dogs: 2-year morphometric results of the dental implant-bone interface. *Int J Oral Maxillofac Implants*. 1996;11:15–25.

3. Proussaefs P, Lozada J. Evaluation of two vitallium blade-form implants retrieved after 13 to 21 years of function: a clinical report. *J Prosthet Dent*. 2002;87:412–415.

4. Roberts RA. Types, uses, and evaluation of the plate-form implant. *J Oral Implantol*. 1996;22:111–118.