

# Food and Drug Administration: Reclassification of Blade Form Dental Implants

Dear Editor,

On July 18, 2013, Dr Ralph Roberts and I testified before the U.S. Food and Drug Administration's Dental Products Panel of the Medical Devices Committee, Docket No. FDA-2012-N-0677, Blade Form Endosseous Dental Implants. The panel acted responsibly and elected to reclassify blade form endosseous dental implants from a Class III to Class II medical device. Blade forms are now in the same classification as root form dental implants. This is significant because there have been several past attempts to reclassify blade form implants over the last 2-1/2 decades. The panel was composed of numerous dental and medical academics, representatives from the medical device industry, and patient and consumer interest groups.

The significance of this reclassification impacts the manufactures in a positive manner. Class III devices, which are considered high risk, require general and special controls and a premarket approval (PMA). The PMA is a considerable financial burden of several million dollars to the manufactures of medical devices. Class II status, for a medium risk device, requires the rigorous 510(k) application process, and associated fees of approximately \$100 000.00, exclusive of any clinical trials and without the financially burdensome PMA. The panel extensively deliberated on the safety, training, and efficacy of blade form dental implants. Dr Roberts, the coinventor of blade form dental implants, discussed the history of the development of blade forms and presented his cases with over 43 years of absolute successful service in atrophic bone. Drs Ralph and Harold Roberts, coinventors of the blade form and ramus frame dental implant, collaborated for many years,

developing workable solutions for the multitude of edentulous patients. I took keen notice of how he simply and predictably restored full arches with the ramus blade, ramus frame, anterior segment, and STR dental implants. The genius is in the simplicity! Dr Roberts solved, in an uncomplicated manner, many problems that we still have with root forms by using blade dental implants. By presenting several histology studies performed by Dr. Leonard I. Linkow, I made the point that blade forms osseointegrated. I presented several of my cases with over 18 years of service in atrophic bone, with some cases utilizing preangled STR blades in lieu of sinus augmentation. The pre-angled STR transforms treating the vexing posterior maxilla into an easily and quickly restorable region. I also presented a time and cost comparison of blade form verses root form cases and the parameters that assure success of blade form cases. Dr Roberts and I both made the case that the art of blade form implants can be taught to motivated and skilled dentists, be predictably placed and restored, and that blade form dental implants have passed the test of time. Blade form dental implants can be used in areas where root forms are placed, but they are a game changer in the atrophic ridge where many times questionable, extensive, and expensive bone grafting is employed with associated morbidity. I am of the opinion that a true oral implantologist knows how and when to place and restore blade form and subperiosteal dental implants in addition to root forms. Hopefully this decision is a turning point for implant dentistry!

I thank the following doctors, with whom I conferred in preparation for this endeavor: Cindy Vu, C. Benson Clark, Raul Mena, Wayne O'Roark, Jack E. Lemons, and John Brunski. I am especially grateful to Dr Leonard I. Linkow for being my dental implantology mentor and his suggestions

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DOI: 10.1563/AAID-JOI-D-13-00230

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during this process. I also thank Dr Linkow for his prolific contributions and enduring dedication to dental implantology. I am indebted to Prof Maurice Valen for his invaluable assistance with my preparation for this hearing, and this wonderful academy for the training I have received. I especially thank Dr Ralph Roberts for asking me

to participate in this process and for his tireless efforts and significant contributions to dental implantology.

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**Note from the Editor-in-Chief:** Please see the Editorial to appear in the next issue, 40(1), February 2014, for further comment about this topic.