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XIII. SAFE MEDICAL DEVICES ACT SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)

I. Classification Name and Number: Endosseous Implant (76DZE),

II. Common/Usual Name: Dental Implant, Endosseous, Post (or screw)-type, titanium or titanium alloy.

III. Proprietary Name: CRYSTAL and CRYSTAL-PLUS Implants System

IV. Classification: This device was classified by the Dental Devices Panel (Title 21 CFR 872.3640.

V. Brief Literature Review

Endosseous implants, and especially those of titanium or titanium alloy, in the "post" or "screw" configuration, have been proved safe and effective through the years. The possible adverse effects summarized in this 510(k) cover those listed by the United States classification panel [Federal Register, vol. 45, No. 251, pp 86025-6, Dec. 30, 1980], as well as to those revealed in a recent literature search. Matukas, "Medical Risks Associated with Dental Implants," states, "Little or no hard data could be found on the medical risks associated with [dental] implants." Because of the wide-spread usage of dental implants, Smith and Zarb made a careful review of the literature and proposed criteria for implant success.

A thorough computerized Medline literature search produced 579 entries. An update of this search produced 60 new review articles. The Journal of Dental Education published a special issue "Proceedings of the Consensus Development Conference on Dental Implants [National Institutes of Health, Bethesda, MD, June 13-15, 1988], Vol. 52, No. 12, pp. 677-831, Dec. 1988. This added to the literature search above, with some especially pertinent reprints from the scientific literature, provide a comprehensive summary of available scientific data.

Zarb completed his report of the detailed Toronto 10-year study by concluding that "the tried and tested Branemark implant technique has revolutionized the treatment options open to the prosthodontist. For the edentulous patient...the prospect for a lifetime of restored oral comfort, function, and appearance have now become predictable and reliable." These results are ample evidence of the safety and effectiveness of these endosseous implants.

VI. These devices are manufactured from the titanium materials proved effective by the above summarized years of clinical usage, sterilized by the standard methods of radiation or ethylene oxide, and are constructed according to methods in the cited substantially equivalent products. Thus, they involve no new types of technology and no new technological questions.