K962130

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VI. 510(k) Summary of Safety and Effectiveness

A. Name and Address

This Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc. 777 Oakmont Lane, Suite 100, Westmont, IL 60559. The telephone number is (708)654-9100. The contact person will be the Director, Regulatory Affairs. This summary was prepared on May 31, 1996.

B. Name of the Device

This device is generally known as an endosseous implant with the trade name "Nobelpharma BRÅNEMARK SYSTEM® - Mk II Self-Tapping Fixture. This submission is a modification to a previously cleared device of the same name in K945398.

C. The Predicate Product

The predicate product used in this Premarket Notification is the previous version of the same device, Mk II Self-Tapping Fixture in sizes 5.0 and 5.5 mm diameter and varying lengths, K945398.

D. Description of the Device

The Nobelpharma BRÅNEMARK SYSTEM - Mk II Self-Tapping Fixture is a line of endosseous implants, varying in diameter, which are implanted in the upper and lower jaw bone to be used to support prosthetic devices to help restore chewing functions of edentulous patients. The device has been cleared for sizes 3.75, 4.0, 4.4, 5.0 and 5.5mm diameters. The only modification is to the 5.0 and 5.5mm diameter fixtures. This modification of the 5.0mm and 5.5mm diameter fixtures entails 1) an increased internal

thread diameter for insertion of appropriate abutment screws and 2) an increased hexagonal dimension for the hex portion of the fixture to facilitate accurate seating of appropriate abutments. An additional minor modification to the flange (a 0.4mm increase of diameter) and to the apex (a 0.3mm increase in diameter) is being made to the 5.5mm fixture to accommodate the surgical and prosthetic components of the system.

E. Intended Use of the Device

The Nobelpharma BRÅNEMARK SYSTEM - MK II Self-Tapping Fixtures are intended to be used in edentulous and partially edentulous patients to restore chewing functions.

F. Comparison of Technological Characteristics

The technological characteristics between the previously cleared 5.0 and 5.5mm diameter Mk II fixtures are identical. The material used in both devices is the same as is the general shape and structure. The only changes for both the 5.0 and 5.5mm diameter fixtures are minor dimensional changes to accommodate placement of the appropriate abutment screws and abutments.