K962403

SEP - 6 1996

VII. 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. Their telephone number is: (708) 654-9100 and the contact person will be the Director, Regulatory Affairs. This summary was prepared on June 19, 1996.

B. Name of the Device

This consists of numerous components to be used in conjunction with the BRÅNEMARK SYSTEM® - Wide Platform Fixtures, including Hand Instruments, Healing Abutments, Impression Copings, Machine Instruments and accessories specific to the MirusCone and CeraOne system.

C. The Predicate Product

The predicate products used in this Premarket Notification are other components marketed by Nobelpharma including the Drills, K925770, Screw Taps, K925768, Hand Instruments, K925774, Healing Abutments, K925779, Cover Screws, K925771, Machine Instruments, K925775, and accessories to the MirusCone K961728 and CeraOne K961737 system.

D. Description of the Device

The Nobelpharma BRÅNEMARK SYSTEM® - Wide Platform Accessories are components used with various BRÅNEMARK SYSTEM® Wide Platform Fixtures. They include Abutments, Healing Abutments, Hand Instruments, Impression Copings and Machine Instruments.

E. Intended Use of the Device

The Nobelpharma BRÅNEMARK SYSTEM® - Wide Platform Accessories are intended to be used as accessories in conjunction with the Wide Platform endosseous implant system and in the exact same manner as their counterpart predicate product.

F. Comparison of Technological Characteristics

The technological characteristics between the components of Wide Platform Accessories and the corresponding predicate product, a comparable component in the BRÅNEMARK SYSTEM®, are identical.