

K961737

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Pre-Market Notification  
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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. Their telephone number is (708) 654-9100. The contact person will be the Director, Regulatory Affairs. This summary was prepared on May 1, 1996.

B. Name of the Device

This device is known as an abutment to an endosseous implant with the trade name BRÄNEMARK SYSTEM® CeraOne Abutment System. This submission is a modification to a previously cleared device under K910611.

C. The Predicate Product

The predicate product used in this Premarket Notification is the previous version of the same device, CeraOne Abutment System, K910611.

D. Description of the Device

The Nobelpharma CeraOne Abutment System is an abutment used with an endosseous implant which is implanted in the upper or lower jaw bone. The CeraOne System allows the prosthesis to be cemented directly to the abutment rather than requiring an additional screw connection. The modifications to the device are the broadening and narrowing of the base and external diameters of the abutments; and broadening and narrowing of the diameters of the abutment screws, adding two series of abutments fitting to larger and smaller diameters of fixtures previously cleared.

E. Intended Use of the Device

The Nobelpharma CeraOne Abutment System is intended to be used to anchor single tooth prostheses in partially edentulous patients.

F. Comparison of Technological Characteristics

The technological characteristics between the modified version of the CeraOne Abutment and the earlier version are identical. The only changes are minor dimensional changes to the diameter of the abutment base and the abutment screw.