

Dental Implant & Attachment Systems  
600 Paisano NE  
Albuquerque, NM 87123

**510(K) SUMMARY**

K961665

April 22, 1996

Contact Person: David D. Dalise  
President / owner, "O" Company, Inc.

Trade Name: "O" Butment ET Implant  
Common Name: Endosseous Screw Implant  
Classification Name: Dental Implant Endosseous / Code 76DZE

Substantial Equivalence to: "O" Butment ES Implant referenced as K923889 and  
Screw-Vent Implant referenced as K900179

Description of Device: A cylinder shaped commercially pure titanium dental  
implant with external threads.

Intededed Use: The titanium endosseous implant is a device intended to be surgically  
placed in the bone of the upper or lower jaw arches to provide support for  
prosthetic devices.

Substantial Equivalence: Substantial Equivalence for the "O" Butment ET Implant is  
based on the following comparison of predicate devices such as "O"  
Company's "O" Butment ES Implant and Dentsply's Screw Vent  
Implant. The design, function, labeling, material composition and intended  
use is equivalent to the devices currently marketed.

Non-clinical tests: Based on lateral and vertical stress analysis performed by Rocky Mountain  
Testing, it has been determined that the physical integrity of the implant  
has not been compromised by the modifications.

This data supports our determination that the "O" Butment ET Implant is substantially equivalent to the  
"O" Company's "O" Butment ES Implant (K923889).