

K965135

FEB 25 1997

LIFECORE

BIOMEDICAL

510(k) Summary

VII Summary of Safety and Effectiveness As required by 807.92(c).

1. This summary of Safety and Effectiveness is being submitted by:
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Date: December 13, 1996

2. Trade Name: Lifecore Conical Abutment
Common Name: Conical Abutment
Classification Name: Precision Attachment for use as an
accessory for Class III Endosseous Implants (per 21 CFR
872.3165).
3. Equivalent Device: The device is substantially equivalent to the commercially marketed products known as Lifecore Conical Abutments Systems (K924589, K954512), Brånemark Miruscone Abutment System (K944964, K961728), 3i Microminiplant System (Catalog # MCA 31-MCA 34), and Steri-Oss HL Abutment System (Catalog # 2854-2857).
4. Device Description: The conical abutment is designed for use with an endosseous implant which is implanted in the lower or upper jaw. The conical abutment provides a base for the restorative crown or bridgework.
5. Intended Use: Implant systems are for use in single tooth, partially edentulous, completely edentulous, mandibles and maxillae as a support or attachment for prosthetic restoration. The restoration can be detachable (screw retained) prosthetics in multiple, free standing or terminal restorations.
6. The technological characteristics of the modified version of the conical abutment and the earlier versions are identical. The titanium used in both devices is the same. Manufacturing processes are also the same as is general shape and structure. Therefore, no new types of technology and no new technological questions are involved.

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