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510(K) SUMMARY

RELEASABLE THROUGH FREEDOM OF INFORMATION

Pursuant to 513(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Calcitek, Inc.
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Registration Number:	2023141
Contact Person:	Donna K. Howard
Date Summary Prepared:	June 28, 1996

Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	Spline X Endosseous Dental Implant System

The primary device used for comparison purposes in this summary is Calcitek's existing Spline Dental Implant System. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. **Intended Use:** The statements of intended use are identical.

   "For use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement."

2. **Description:** These Class III dental implants are supplied sterile, ready for placement by a licensed dentist. There has been no significant change to the prosthetic components.

3. **Technological Characteristics**

   Design: There has been no significant change to the overall cylindrical geometry of the implant body or the Spline interface/abutment system. The only difference is the use of a porous titanium coating.

   Materials: The materials used for the Spline X Endosseous Dental Implant System (Ti-6Al-4V) are the same as previously mentioned in the premarket notification.

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4. **Comparison Analysis:**

The overall design of the implants is similar to currently cleared Spline Dental Implant Systems. Prostheses are identical to the Spline predicate devices. The subject implants are coated with a porous coating made from the same titanium material (Ti-6Al-4V) as used in predicate devices.

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