

K 962120

Original 510(k)
Tomograph Accessories

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23

Section 7

510(k) Summary

Manufacturer Information:

Submitter's Name: Steri-Oss Inc.
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U.S.A.
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Device Names:

Common Name: Tomograph accessories
Trade Name: None
Classification Name: Tomographic X-ray system

Predicate Device:

Substantial equivalence is claimed to Siemens Orthophos Plus.

Device Description:

How device functions: Steri-Oss has designed a series of products to be used as a complement to a tomography system. These products aid in the positioning of dental patients for radiological imaging.

Device Description (cont.):

Scientific concepts: A tomograph has the ability to take a cross-sectional view of dentition. In order to optimize the results obtained from tomography, patient positioning indices may be used.

Characteristics: The products submitted are manufactured of varying materials and are designed to assist in the use of a tomographic x-ray unit.

Intended Use:

The tomograph accessories are indicated for use in conjunction with a tomographic x-ray system to produce radiological images.

Comparison to Predicate:

The Siemens Orthophos Plus product is designed to take radiological images. As a built-in feature of this unit, it contains built-in components to aid in the positioning of the dental patient while the image is being taken.

Steri-Oss' products are designed to aid in the positioning of the dental patient as well; however, the products are intended to be supplemental to existing radiographic units.

Performance Data:

Not applicable.