

K963860

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**Appendix 1 510(k) Summary (pursuant to 513(l))**

**Summary of Safety and Effectiveness  
NOMOS TALON™ Positioning and Immobilization System**

Pursuant to Section 513(i) of the Federal Food, Drug, and Cosmetic Act

**I. General Information:**

**Trade/Proprietary Name:** The NOMOS TALON Positioning and Immobilization System

**Common/Usual Name:** Patient Positioning/Positioning and Immobilization System

**Classification Name:** Medical Charged Particle Radiation Therapy Systems and Accessories

**Applicant's Name and Address:**

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**II. Name of predicate device(s):**

TALON Skull Mount:

RSA XKnife Radiosurgical System/BRW Stereotactic System (K811452, K912630 and K923522)

TALON Skull Mount and NOMOGrip:

NOMOS ReFix™ System (K930279B)  
gNomos Stereotactic System for neurosurgery (K901670B)

Targeting Box:

CT & MR frame from BRW Stereotactic System (K811452)

CT Reference Pointer:

Vertical post of gNomos Stereotactic System (K901670B)

Radiotherapy Table Adapter:

ReFix Radiotherapy Table Adapter (K930279B)

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**CT Head Support:**

ReFix CT Head Support (K930279B)

Each of these devices has been marketed prior to and/or following enactment of the Medical Device Amendments in May, 1976.

**III. Classification:**

Medical Charged Particle Radiation Therapy Systems and accessories are Class II (21 CFR 892.5050) - Radiological Devices Panel.

Radiographic Head Holders are Class I (21 CFR 892.1920) and are exempt from the premarket notification procedures in Subpart E and Part 807.

**IV. Performance Standards:**

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

**V. Intended Use and Device Description:**

The NOMOS TALON Positioning and Immobilization System is intended to provide an invasive means to repeatedly position and immobilize a patient during:

- a) diagnostic procedures in preparation for radiation therapy (RT) treatments of the head or head and neck, and
- b) during treatment procedures in the radiation therapy suite.

A description of the function(s) of the major components follow:

The TALON Skull Mount is an invasive means of repeatedly positioning and immobilizing a patient during diagnostic imaging and/or therapeutic administrations of radiation therapy (RT).

The NOMOGrip is a rigid bracket that attaches the TALON Skull Mount to the Radiotherapy Table Adapter or CT head support.

The Target Box is an external, removable frame designed to permit positioning of the patient with respect to the lateral lasers and defining light field from the linear accelerator.

CT Reference Pointer is a pointer which attaches with 2 screws to the NOMOGrip and produces a reference pointer on the CT scans.

Radiotherapy Table Adapter attaches to the treatment couch and provides an attachment point for the NOMOGrip during treatment.

CT Head Support attaches directly to the CT imaging couch and provides an attachment point for the NOMOGrip during imaging.

## **VI. Summary of Substantial Equivalence:<sup>1</sup>**

**Indications:** The indications for use are the same as the predicate NOMOS ReFix System (K930279B) and are similar to the other predicate devices.

**Design:** The design is similar to the components of the predicate NOMOS gNomos Stereotactic System (K901670B) and components of the predicate NOMOS ReFix System (K930279B).

**Materials:** The implanted material (Skull Screws) is similar to the material used in the predicate NOMOS gNomos Stereotactic System (K901670B). The non-implanted materials are the similar to those used in the NOMOS ReFix System (K930279B).

**Manufacturing:** The manufacturing processes are the same as those used in the NOMOS ReFix System (K930279B) and the gNomos Stereotactic System (K901670B).

**Specifications:** The specifications for repeat fixation are similar to those of the NOMOS gNomos Stereotactic System (K901670B).

**Conclusions:** The indications, design, materials, manufacturing, and specifications of the NOMOS TALON Positioning and Immobilization System do not raise any new issues relating to safety and effectiveness. NOMOS thus considers the NOMOS TALON Positioning and Immobilizing System equivalent to the predicate devices for positioning and immobilization of the head in therapeutic administrations of radiation.

<sup>1</sup>Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "... a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).