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**Appendix 1 510(k) Summary (pursuant to 513(l))****Summary of Safety and Effectiveness  
The NOMOS® MINICRANE™**

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

**I. General Information:**

**Classification Name:** Accessory to Powered Radiation Therapy Patient Support Assembly  
**Common/Usual Name:** Caliper  
**Trade/Proprietary Name:** NOMOS® MINICRANE™  
**Applicant's Name and Address:**

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

NOMOS CRANE (K941927)

**III. Classification:**

Powered Radiation Therapy (RT) Patient Support Assembly Accessories are Class II (21 CFR 892.5770).

**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:**

*Intended Use:* The NOMOS MINICRANE is intended to be used as an accessory to radiation therapy patient support assemblies. The MINICRANE is used to provide a simple method for indexing the patient/table a prescribed distance.

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**Device Description:** The MINICRANE is an accessory to radiation therapy patient support assemblies which attaches to the an appropriate part of the radiation therapy table (table) such as the side (hand) rails or a fixation device such as the NOMOGrip. The arm of the MINICRANE is available in a number of lengths to accommodate various treatment positions. The MINICRANE locks onto the table or fixation device. Patient access to the treatment table is not obstructed and the table can be freely adjusted in the X, Y, and Z axes. The arm of the MINICRANE incorporates a battery-operated digital micrometer which displays, in millimeters, the position of the table with respect to an origin. The micrometer may be set to display the value in inches, however, the Operator's Manual instructs the user to set the micrometer to display millimeters. With the MINICRANE attached to the treatment table, a technologist can move the table to a predefined point in the Y axis. The coordinate of the MINICRANE will identify this point within the limits of accuracy of the stability of the treatment table.

## **VI. Summary of Substantial Equivalence:**

**Indications:** The indications for the NOMOS MINICRANE are the same as those for the predicate NOMOS CRANE; i.e., to display the prescribed distance of patient indexing.

**Design:** The design of the NOMOS MINICRANE is similar in concept to the relevant feature of predicate NOMOS CRANE.

**Materials:** The materials used in the NOMOS MINICRANE are similar to those used in the relevant feature of the predicate NOMOS CRANE.

**Manufacturing:** The manufacturing processes used in the NOMOS MINICRANE are similar to specific aspects used in the manufacture of NOMOS CRANE.

**Specifications:** The specifications of the NOMOS MINICRANE are similar to the predicate NOMOS CRANE.

**Conclusions:** The indications, design, materials, manufacturing, and specifications of the NOMOS MINICRANE do not raise any new issues relating to safety and effectiveness.

NOMOS thus considers the NOMOS MINICRANE equivalent to the predicate NOMOS CRANE.

**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).**

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