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Summary of Safety and Effectiveness P192

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1. Submittor's Information: Dated: July 19, 1996

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2. Common or Usual Name: Brachytherapy Treatment Planning
Proprietary Name: Helax TMS Brachy Version 3.0
Classification Names: Class: II, Product Code: 90 LHN

3. Predicate Device: **PLATO** Radiotherapy Treatment Planning System, **NUCLETRON** Corporation, Columbia MD (USA) K915622

4. Description of Device:

TMS Brachytherapy is an integrated work module for treatment modelling of interstitial and intracavity Brachytherapy treatment techniques. The work module is designed to assist in treatment planning in accordance with the broad range of clinical routines and therapy techniques. The TMS Brachytherapy work module provides support in treatment design by supplying tools for source channel definition, source positioning, manual optimisation of source weights, presentation of dose distributions, and point dose values in arbitrary sections and evaluation of treatment tactics. The structure of the work module parallels that of the external beam module in the design of the user interface.

5. Statement of Intended Use:

The TMS Brachytherapy Module, Version 3.0, is a 3D Radiotherapy Treatment Planning (RTP) system for radiation dose planning of patients undergoing interstitial or intracavitary treatment in the Oncology clinic. The system software is designed to function as an integrated part of the TMS (Treatment Management System) radiotherapy treatment planning system (K953391). The TMS Brachytherapy Module is used for planning the treatment only, not for performing the treatment.

The intended use is the same as the predicate device.

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6. Technological Characteristics

The predicate device is presently in commercial distribution in the United States. The TMS Brachytherapy system has the same technological characteristics and is similar in design, function, and application to the predicate device.

The Technological Characteristics are the same as the predicate device.

7. Differences:

There are **no differences** between the technology of the predicate device and the Helax TMS Brachy Version 3.0 system. Minor differences in configuration and specifications as noted in the predicate device comparison chart do not alter the intended use or affect the safety and effectiveness of the TMS Brachytherapy system when used as labeled.

8. Performance Evaluation:

The test results summarized in the Summary Test Report and in the Safety and Effectiveness Test Report indicate that the TMS Brachytherapy system consistently performed within its system requirements specifications and equivalently to the predicate device.