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MLC Fit Non-Confidential Summary of Safety and Effectiveness

The primary function of MLC Fit is to provide a means to define multileaf collimator leaf plans based on a user defined shape of a desired treatment area for use with a cancer radiotherapy treatment machines equipped with a multileaf collimator manufactured by Siemens Medical Systems and Varian Associates. Users may create, view, and edit MLC leaf data as well as other geometric parameters associated with treatment field definitions. An intended use statement for MLC Fit is contained in Exhibit 2a of this submission.

The goal of MLC Fit is to provide the leaf positions for a given treatment shape in a manner that eliminates the slow and error prone method of hand calculating the position for each leaf and manually setting up the leaf plans. MLC Fit allows the users to define treatment field shapes and generate multileaf collimator leaf plans based on that input shape. Leaf positions and other geometric parameters can be adjusted to meet the user's clinical requirements. MLC Fit is not capable of moving the leaves or other parameters to the calculated positions; it only provides the definition of the treatment field as a hardcopy and to a database file.

The primary functions of MLC Fit are, in effect, the same as those of the Philips MLC Prescription Entry System (see Exhibit 3b). Both systems supplement the MLC treatment field definition process only, and do not attempt to control the movement of the defined parameters.

IMPAC Medical Systems, Inc., has gained a reputation of providing high quality software products which serve the cancer therapy community. One reason we have earned this reputation is that we strive to provide end-user process oriented solutions with our products. Another reason is that software development for cancer therapy is our only business. This allows us to stay focused on administering development processes designed specifically for a software business. Strict adherence to these processes will assure that MLC Fit is a safe and effective product suitable for use as intended in a cancer therapy department.

MLC Fit was developed according to IMPAC Medical Systems, Inc.'s approved Software Development Standard (Exhibit 9). This standard governs the process by which systems and software development are to be defined, implemented, tested, released, installed, and supported. In addition, this standard outlines how IMPAC conforms to the Good Manufacturing Practices (GMP) requirement required by the Safe Medical Devices Act of 1990.

Per the guidelines set forth in the Software Development Standard, MLC Fit was developed per Software Requirements Specifications and documented with Software Design Descriptions. Samples of these are shown in Exhibits 4 and 5 for your review.

In addition, a Hazard Analysis was performed to determine and evaluate the areas which represent potential hazards during MLC Fit operation. For hazards within the scope of the MLC

Fit product, the hazard, effect, and protection implemented were documented and reviewed. The System Hazard Analysis is included in Exhibit 6.