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知勉工業股份有限公司

MAKRITE INDUSTRIES INC.

11F-5, No.79, Sec.1, Hsin Tai Wu Rd, His-Chih, Taipei Hsien Taiwan, R.O.C. (FAR EAST World Center)

TEL: 886-2-26982419 FAX: 886-2-26982423

Date: May, 6, 2011

Subject: Risk Analysis for Makrite's 9500-N95 Mask

To: **Letter to the 510(k) File**

From: Bob Wen, Vice Chairman, Makrite Industries, Inc.

MAKRITE MODEL 9500-N95 RESPIRATOR AND SURGICAL MASK

The Model 9500-N95 has been designed as the ultrasonically head strap welded version of the MAKRITE TYPE N95 RESPIRATOR AND SURGICAL MASK MODEL 910-N95. The 910-N95 cone shaped medical mask is the subject of K020474. This letter to file documents the process whereby Makrite has determined that the new model, 9500-N95, is covered by the original Premarket Notification, K020474, and does not require a separate, new 510(k) application.

The materials in both masks are identical, as shown in the product specifications. The Model 9500-N95 meets the same performance specifications as the original 910-N95 mask.

The FDA guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device" was used to reach the determination that the change may be documented to file. Specifically, Flow Chart B in the guidance differentiates between changes in specifications that require a new 510(k) and those that do not. A copy of Flow Chart B, marked to show the decision path, is attached to this letter to file.

Makrite followed the procedures under the Design Changes portion of its Quality System to determine required verification and validation for the change. The new model meets the Design Control requirements in Makrite's Quality System. As noted, Design Validation testing demonstrates the new model meets the same performance specifications as the original and does not raise any new questions of safety or effectiveness.

Attachments:

1. Flowchart B from the 510(k) change guidance.

Bob Wen, Vice Chairman, Makrite Industries, Inc.

FLOWCHART B - IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?