

RAULAND-BORG CORPORATION

1802 WEST CENTRAL ROAD • MOUNT PROSPECT, ILLINOIS 60056-2230 **t** 847.590.7100 **f** 847.632.8530

November 3, 2015

To: All Rauland Customers

From: Donna Djinovich

Director, Regulatory Affairs

Re: U.S. Food and Drug Administration (FDA) Medical Device Registration Status

In compliance with United States Food and Drug Administration (FDA) regulations, Rauland is registered as a domestic Medical Device Manufacturer (Facility Registration # 1000227151).

As a Medical Device Manufacturer, Rauland is subject to 21 CFR 820 Quality System Regulations (QSR's), a stringent set of design and manufacturing requirements intended to ensure the highest standards of device performance, quality, and safety. Rauland is also subject to routine FDA inspection and surveillance.

To view Rauland's FDA registration, please go to:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm

Input: Establishment Name: Rauland