Rauland-Borg Corporation
3450 West Oakton Street
Skokie, IL 60076 USA

Date: July 18, 2008

To: Rauland Customers

From: Jonathan Wacks
Director, Regulatory Affairs

Re: United States Regulatory Status-Responder Nurse Call Systems

In order to provide our customers with a better understanding of Rauland's Responder Product line, please note the following:

1. The Responder IV and 4000 systems are considered medical devices by the US Food and Drug Agency (FDA), and are subject to federal regulation.

2. As such, Rauland is a registered medical device manufacturer with the US Food and Drug Agency (Registration Establishment # 1000227151).

3. Based upon FDA's device classification system, Rauland's Responder product line has been listed under 21 CFR 890.3725 Powered Environmental Control System, (Class II medical device).

4. Pursuant to the 1997 FDA Modernization Act, Rauland's Responder product line is no longer subject to the 510(k) device submission requirement (Class II "exempt").

5. As a Class II exempt medical device, Rauland is required to comply with the Quality System Requirements (QSR's), Medical Device Reporting (MDR), and other provisions intended to provide our customers with the highest levels of quality assurance and product safety.

6. To view Rauland's establishment and device listing with US FDA, go to:

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

Type in "**Rauland**" in the "Establishment Name" field, and click on the "SEARCH" button.

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Device Listing Database

Proprietary Name:	RESPONDER
Classification Name:	SYSTEM, ENVIRONMENTAL CONTROL, POWERED
Product Code:	IQA
Device Class:	2
Regulation Number:	890.3725
Medical Specialty:	Physical Medicine
Registered Establishment Name:	RAULAND-BORG CORPORATION
Registered Establishment Number:	1000227151
Owner/Operator:	RAULAND-BORG CORPORATION
Owner/Operator Number:	9075142
Establishment Operations:	Manufacturer

Database Updated 04/08/2008