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JUL -5 2001

WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

VIA FEDERAL EXPRESS

SEDECAL SA (Sociedad Espaloa  
de Electromedicine y Calidad S.A.)  
Pelaya 9,  
Poligono Industrial Rio De Janeiro  
Madrid E-28110 Spain

Dear Sir/Madame:

During a review of import records for your firm SEDECAL, Madrid, Spain, we have determined your firm has introduced electronic products into United States (U.S.) commerce. Specifically, your firm has imported into the U.S. the following electronic products to [REDACTED], Wheeling, Illinois:

Product	Number of Products Imported	
	2000	2001
X-Ray Generator	[REDACTED]	[REDACTED]
X-Ray Mobile System	[REDACTED]	[REDACTED]
X-Ray Equipment	[REDACTED]	[REDACTED]
Vet System	[REDACTED]	[REDACTED]
Parts for X-Ray	[REDACTED]	[REDACTED]

Our records indicate your firm has introduced into U.S. Commerce products without a 510(k) that require a 510(k) and products without an initial report that require an initial report.

Manufacturers of electronic products and medical devices are required to take certain actions before they may introduce a product into U.S. Commerce. For example:

1. Manufacturers are required to file an initial product report for X-ray generators.
2. Manufacturers are required to file an initial product report and obtain 510(k) approval for diagnostic X-ray systems.
3. Manufacturers are required to file an abbreviated product report for veterinary systems.

4. Manufacturers of an electronic product shall designate a permanent resident of the U.S. as the manufacturer's agent upon whom service of all processes, notices, orders, decisions and requirements made for and on behalf of the manufacturer.

You should immediately cease the introduction of your products into U.S. Commerce until all the requirements of the Federal Food, Drug, and Cosmetic Act (Act) have been completed. Within fifteen (15) working days from the date you receive this letter, please supply this office with a list of model numbers, a brief description of each model, and list of the importer of record for each model of product that you have introduced into U.S. Commerce. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Heyward Rourk, Diagnostic Devices Branch, Office of Compliance (HFZ-322), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

Because you do not have marketing clearance for your X-ray equipment, marketing this equipment in the U.S. is a violation of U.S. law. In legal terms, the product is misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

Because you have imported diagnostic X-ray components or X-ray systems that do not have a product report, marketing this equipment in the U.S. is a violation of U.S. law. In legal terms, your product appears to be an electronic product that does not comply with an applicable standard. Your product does not comply with an applicable standard because no reporting has been provided as required by section 536(a) of the Act.

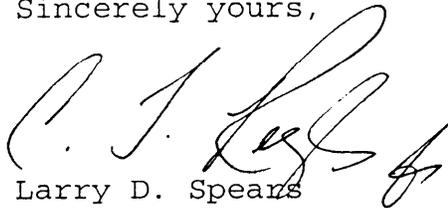
You should know that these are serious violations of the U.S. law and failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include seizing your U.S. product inventory and placing your products on import detention.

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Finally, you should understand that there are many Food and Drug Administration (FDA) requirements pertaining to the manufacture and marketing of medical devices and electronic products. This letter pertains only to the issue of premarket clearances and initial product reports for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices and electronic products by contacting our Division of Small Manufacturers Assistance at (800) 638-2041 or through the Internet at <http://www.fda.gov>.

If you have specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Heyward Rourk at (301) 594-4591.

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. D. Spears", with a stylized flourish at the end.

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health