



JUL 7 2000

CERTIFIED MAIL – RETURN RECEIPT REQUIRED

DRA. Olga Z. De Kleiman
175-101 Cuernavaca St.
Col. Condesa
Mexico City, Mexico 06040

RE: Little Sentry Junior
Infant Breathing Monitor

Dear Ms. De Kleiman:

We are writing to you because we are in receipt of information from your firm's website, <http://www.angelfire.com/ok/muertedecuna/Eningles.html>, which indicates that your firm may be marketing the above referenced product in the United States. Under a United States law, this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

The law requires that the manufacturer or the distributor of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country.

A review of our records has determined that you have not obtained marketing clearance for your device, which you may be offering for sale in this country. The kind of information you need to submit in order to obtain this clearance is described in the enclosed manual. The FDA will evaluate this information and decide whether your product may be legally marketed.

Please let this office know in writing within thirty (30) days from the date you receive this letter what steps you are taking to correct the problem if your firm is indeed marketing this product in this country. Alternatively, if your firm is not marketing this product in this country, please let this office know in writing within thirty (30) days from the date you receive this letter what steps you are taking to ensure that no labeling, including promotional items, indicates that the device is being offered for sale in this country. Please direct your response to:

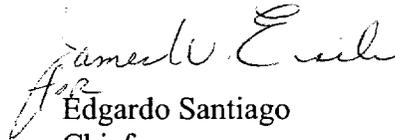
James W. Eisele, Consumer Safety Officer
Office of Compliance
Division of Enforcement III (HFZ-343)

Center for Devices and Radiological Health
2094 Gaither Rd.
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device 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 by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact James Eisele at (301) 594-4659.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Edgardo Santiago".

Edgardo Santiago
Chief

Orthopedic, Physical Medicine and
Anesthesiology Devices Branch
Division of Enforcement III
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: 510(k) Manual