DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

94607d

WARNING LETTER

APR - 9 2004

VIA FEDERAL EXPRESS

Mr. Kevin J. O'Neill, President
Pyng Medical Corporation
#7 - 13511 Crestwood Pl.
Richmond, B.C. V6V 2E9, Canada

Dear Mr. O'Neill:

During an inspection of your establishment located in Richmond, Canada on November 17 - 20, 2003, our investigator determined that your firm manufactures the F.A.S.T.1 intraosseous infusion system. This product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. § 321(h)).

The above-stated inspection revealed that this device is misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as required by section 519 respecting the device and the Medical Device Reporting (MDR) regulation, Title 21 CFR, Part 803. Significant deviations include, but are not limited to, the following:

1. Failure to develop, maintain, and implement proper written MDR procedures, that includes a standardized review process/procedure for determining when an event meets the criteria for reporting, as required by 21 CFR 803.17(a)(2). For example, your firm lacks any medical device reporting procedures that address a standard review process/procedure for determining when an event meets the criteria for medical device reporting (MDR) and reports to the Food and Drug Administration (FDA).

2. Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1). For example, your firm failed to submit MDR reports to the FDA within 30 days for the following complaints: CC051, CC055, CC060, and CC064. These complaint numbers represent events that should have been reported as serious injuries.

3. Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and such

device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example, your firm failed to submit MDR reports to the FDA within 30 days for the following complaints: CC052 and CC072. These complaint numbers represent events that should have been reported as malfunctions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA.

We received your response from Mr. C. Dale Lambert, Quality Manager/Regulatory Affairs dated December 4, 2003, concerning our investigator's observations on the FDA Form 483. We have reviewed the letter and concluded that your response is inadequate for the following reasons:

1. Your firm's response letter stated that Item 1 was addressed at the time of the inspection and was corrected and verified.

   This response is inadequate for the following reasons:

   a) The definition of 'malfunction' under GP-009b, Section 4.3, is inadequate. Your firm's definition is inadequate because it does not include the following: (1) the malfunction involves a long-term implant or a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life; or (2) the manufacturer takes or would be required to take an action under sections 518 or 519(f) of the Act as a result of the malfunction of the device or other similar devices.

   b) The definition of 'becomes aware' under GP-009b, Section 4.5, is incorrect. Your definition does not include the 'and', which separates sections (i) and (ii) of 21 CFR 803.3(c)(2).

2. Your firm's response letter states that the complaints in question were not submitted as MDR's to the FDA because it was your firm's understanding that the complaints did not meet the criteria of the FDA Medical Device Reporting Requirements. Your firm also stated that the device did not malfunction under the definition of the FDA malfunction, nor caused or contributed to death or serious injury.

   This response is inadequate.

> Serious injury means an injury or illness that necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

3. Response is the same as in observation #2.

This response is inadequate.

> A malfunction is reportable if the malfunction involves a long-term implant or device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed.

Please notify this office in writing within fifteen (15) working days from the date you received this letter, of the specific steps you have taken to correct the noted violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, please include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, General Hospital Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Alan Stevens.

If you need help in understanding the contents of this letter, please contact Alan Stevens at the above address or at (301) 594-4616 or FAX (301) 594-4638.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health