

GENDEX-DEL

GENDEX-DEL Medical Imaging Corp.
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Food & Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

To Whom it May Concern,

Pursuant with the request for comments on refurbishments, rebuilder, reconditioners, servicers, and "as is" marketers of Medical Devices should fall under GMP regulations.

As a manufacturer, I view the aforementioned markets as essentially the same as us, we both supply the market with Diagnostic Medical X-Ray equipment. And as such, since the intended use is exactly the same, for use on humans as opposed to dogs and cats, I feel strongly that we all should be subject to the same "ground rules" commonly referred to as "QSR". I do, however, see problems with your offices monitoring companies for compliance that are, most of the time, smaller than original manufacturers.

Most manufacturers invest significantly in Regulatory Affairs professionals that assure that their company is compliant, and remains current in the changing regulations. I think the secondary market may take an issue with this, however, the possible negative impact to the population far outweighs the investment in a full Compliance Program that most original manufacturers consider standard business.

In summation, medical equipment is medical equipment, regardless of where it comes from.

Sincerely,



Jeffrey N. Moeller, R.T. (R) (ARRT)
Director, Quality and Regulatory Affairs

JNM/sjm

97N-0477

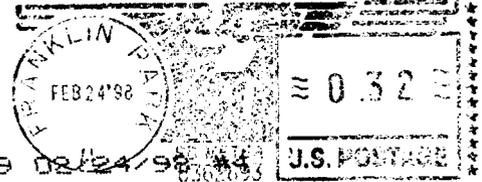
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