

**Benjamin
Biomedical, Inc.**

March 19, 1998

Dockets Management Branch (HFA-305) 3 1 1 6 '98 APR -1 P1:27
Food and Drug Administration
12420 Parklawn Dr., RM 1-23
Rockville, MD 20857

Re: Docket No. 97N-0477, ANPR Remarketing of Used Medical Devices

Comments Submitted By: Benjamin Biomedical, Inc., Joe Morrison Operations
Manager.

Introduction:

Benjamin Biomedical, Inc. is engaged in the repair of medical instruments. Management believes that any proposed regulation will have an impact on the company's business operation.

Introductory Statement:

It is our opinion that regulatory action by the FDA is not necessary at this point in time. Market competition is forcing service companies to implement and adhere to a quality system. This includes certification by qualified third parties, such as ISO 9001 certification. The trend is towards voluntary quality system compliance because many device users require (or strongly favor) that third party service providers be ISO certified. Further, competition within the service market demands top quality performance. If a provider's quality, performance, or service is lacking the provider will not survive in the existing business environment.

At a minimum the industry should be given the opportunity for self-regulation via the implementation of recognized industry standards.

The remainder of these comments will be geared to the specific questions raised in the ANPR.

1. Definitions:

a. Refurbishers. The use of the term "service" as set forth in the proposed definition should not be construed to incorporate all of the requirements of a "Servicer." Further clarification of the language "all functions for which it is designed" should be provided.

b. "As Is" Remarketers: Correct as defined.

97N-0477

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- c. **Service:** We have concern with the definition being dependent on the manufacturer's specifications. Regulations should be based solely upon safety/performance issues. The regulations should not inadvertently provide the manufacturer with opportunity or incentive to draft specifications that are designed to be impossible or (financially impractical) for third party compliance. Inappropriate regulation will hurt the device users and the public by resulting in higher prices and limited service options.
2. **Evidence of Actual Problems:** We have no direct knowledge of patient injury resulting from 3rd party repairs. The performance of repaired or remarketed devices may vary depending upon the circumstances, including the quality of service provided by the remarketer. Any party that provides poor performance, quality or service cannot survive in the remarketing industry.
3. **Appropriate Level Of Control:** Registration, maintenance of complaint and service history files, and event reporting should be mandatory. Additional mandatory requirements, if any, should be appropriate to the level of service (Refurbisher, Servicer, etc.) provided. Third party accreditation should be documented but should remain voluntary.
4. **Levels of Regulatory Compliance:** There should be a minimum level of regulation (see 3 above). Additional requirements, if any, to depend on the level of service the party purports to provide. Where possible, compliance to any regulations beyond the minimum should be voluntary. Where possible, certification by an accredited third party should be one of the recognized methods of compliance.

Conclusion:

Market realities make regulation unnecessary. Self-regulation should be given full opportunity to succeed before government regulation is initiated. If FDA regulation is deemed appropriate, minimum compliance levels should be established. Compliance beyond minimum levels should be optional. Care should be taken that all regulation be limited to that necessary to assure product quality and patient safety. Device users should not be denied access to quality third party repair sources due to inappropriate regulation.

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