



NORTH
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February 27, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0477

Dear Sir or Madam:

The following comments are made on behalf of North American **Dräger** in regard to the advanced notice of proposed **rulemaking** regarding remarketing of medical devices, published in the December 23, 1997 Federal Register (Vol 62, No. 246). North American **Dräger (NAD)** is a manufacturer of anesthesia workstations, patient monitors, and operating room data management systems. NAD also services and **refurbishes** anesthesia equipment.

We are very concerned about the potential risks to the public health and to increased manufacturer's liability that may result from unregulated activities regarding all types of remarketer of used medical equipment. We believe that all remarketer should be required to comply with applicable sections of The Federal, Food, Drug, and Cosmetic Act (the act).

We are aware of several incidents that allegedly were caused by or contributed to by the unregulated activities of refurbishers, servicers and "as is" remarketer. For example:

One incident allegedly resulted in severe permanent brain damage to a child. The device was processed by two refurbishers and installed by a servicer. The alleged serious injury occurred during the first use of the remarketed device (re: **MDR# 25 17967-1996-00001**).

Another incident allegedly also resulted in severe permanent brain damage. An 18 year old anesthesia workstation was sold "as is" to a surgical center. The device did not meet current consensus standards. A physician operating the device allegedly believed that the device monitors activated automatically when power was turned on. The older device was not designed to perform in that manner (re: **MDR# M5235 17**).

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We concur with the agency's expressed belief that the **regulatory** approach for all three types of remarketer should include compliance with requirements concerning:

Representations of quality under section 501(c) of the act (21 U.S.C. 351(c)); false or misleading labeling under section 502 of the act (21 U.S.C. 352), and part 801; notification and recall provisions under section 518 of the act (21 U.S.C. 360h), and part 810; corrections and removal reporting requirements under section 519(e) of the act, and parts 803 and 804; tracking requirements under section 519(e) of the act, and part 821; and radiological health requirements under sections 532 through 542 of the act (21 U.S.C. 360ii through 360ss), including records and initial reporting requirements under part 1002, and standard requirements under part 1020.

So that the agency is aware of remarketing activities, we believe that refurbishers, servicers, and "as is" remarketer should be required to register and that **refurbishers** and "as is" remarketer should be required to list (21 CFR Part 807).

Refurbishers and servicers should be required to comply with the following subparts of 21 CFR Part 820: Subparts B, D, E, F, G, H, J, K, and M; additionally refurbishers should also be required to comply with subparts I and L. We believe that compliance with these subparts provides basic controls for remarketing activities.

Any remarketing activities that could change the finished device's **performance** or **safety** specifications or indications for use should continue to be considered remanufacturing as defined in the CGMP. Remanufactures should continue to be subject to the same regulatory requirements as manufacturers.

In addition, we believe that remarketing of older devices that do not meet current consensus standards presents an increasing risk to public health. We have cited an example of serious injury where a physician was unfamiliar with the safety characteristics of a remarketed 18 year old device. Medical students and residents are trained on state of the art equipment, therefore as medical devices age, a smaller percentage of practicing physicians are familiar with the capabilities of these older devices. The remarketing of older devices into a facility where the medical staff maybe unfamiliar with the device's limited capabilities presents a unique public health risk. We believe that the agency should exercise some control over this situation by requiring that remarketed devices over ten (10) years of age comply with the appropriate current FDA Recognized Consensus Standard(s) before the device is reintroduced into the market.

We believe that these recommendations will reduce the potential for injury or death related to remarketed medical devices. We appreciate the opportunity to comment.

If you have any questions regarding this letter, please contact the undersigned at (215) 721-5400.

Sincerely,


James J. Brennan
Director, Regulatory Affairs

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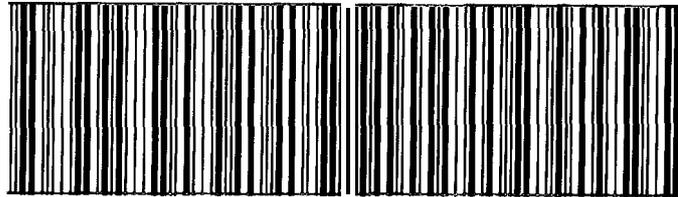
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