



MedEquip

Biomedical Service

Always balanced in the customer's favor!

FDA
DOCKETS MANAGEMENT BUREAU
HAS-305 FDA 12420
TALKLAWN DRIVE ROOM 23
ROCKVILLE MD 20857
3228 APR -6 AIO:19 March 31, 1998

Ladies and Gentlemen,

Medequip Biomedical Service, repairing and inspecting service for medical and laboratory equipment, has been in business for seven years. We have one professional electrical engineer - B S degree Pardue University class of 1986 -, one US Airforce highly trained electrical circuit specialist, one Biomedical Engineer with 16 years hospital experience, one Kissar Collage degree technician - with five years field experience - and one shop technician - expecting a degree in electronics in May 1998. It is with this qualified and experienced staff we disagree with and oppose the ANPR that we believe is restricting and/or will hamper our industry with unneeded requirements. It is our considered opinion - "there is nothing in the industry that we or others are doing that needs regulating in any way!" The ANPR released late last year is not needed and we believe the status quo is doing just fine! Except for the possibility some manufacturing companies may wish to reserve 'repair for themselves', there are no complaints from the end users!

Follow the old saying - "If it ain't broke, don't fix it!" /

Sincerely,

Handwritten signature of Harry Trafford
Harry Trafford, Administrator
For Medequip Repairs, Inc.

97N-0477

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