Medical Device Recall and Risk Factors

The below chart lists types of medical devices and the number of FDA recalls they have had, as well as their risk of lawsuit. FDA recalls of medical devices result in tremendous costs as well as negative publicity, and several of these recalls were due to battery holder or contact failures. However, one thing they have in common is that none of the affected companies' devices used MPD's battery holders or contacts. In fact, many have turned to MPD for solutions to get them back onto the market.

Device Type	*FDA Category*	*FDA Class*	*FDA Recalls**	*Lawsuit Risk*
Accelerometers	*Not FDA Regulated*			Low
Anti-Coagulation Monitors	864.5400	II	10	Medium
Automated External Defibrillators	870.5310	III	87	High
Baby Breathing Monitors	*Not FDA Regulated*			Low
Baby Monitors	*Not FDA Regulated*			Low
Bathroom Scales	*Not FDA Regulated*			Low
Blood Pressure Meters	870.1130	II	21	Low
Body Fat Analyzers	870.2770	II	0	Low
Cholesterol Meters	862.1175	I	0	Low
Electrical Muscle Stimulators	890.5850	II	0	Low
Fertility Monitors	862.1155	II	7	Low
Glucose Meters	862.1345	II	52	High
Impotence Pumps	*Not FDA Regulated*			Low
Insulin Pumps	880.5725	II	9	High
Iontophoresis Devices	890.5525	II	1	Low
Massagers	890.5660	I	3	Low
Nebulizers	874.5220	I	3	Low
Oxygen Conservers	868.5905	II	1	Medium
Pedometers	*Not FDA Regulated*			Low
Pulse Oximeters	870.2700	II	8	Medium
TENS Devices	882.5890	II	0	Low
Thermometers	*Not FDA Regulated*			Low

**As of Aug 15, 2006*

It is important to note how significant the FDA Class of a device is when it comes to the risks associated with a failure of the device. Recalls and lawsuits are both more likely to occur in higher classes. Below are brief descriptions of each of the FDA classes:

Class I Devices which have minimal potential for harm. Most of these devices are exempt from the majority of FDA regulations.

Class II Devices which may cause harm to users, but for which there are special controls to ensure safety and effectiveness. The FDA must be notified before the device may be marketed, the device must be labeled correctly, and Good Manufacturing Practices must be followed. In addition to the above general controls, regulations specific to the device type must be followed.

Class III Devices which sustain life or carry risk of injury. The FDA must approve the device before it may be marketed, in addition to following all Class II regulations.