

ATTACHMENT 1—LIST OF SUDS KNOWN TO BE REPROCESSED OR CONSIDERED FOR REPROCESSING JUNE 26, 2003—
Continued

| | Medical specialty | Device type | 21 CFR section | Class | Product code | Risk* | Critical/semi-critical/noncritical | Premarket exempt |
|----|-------------------|---|----------------|-------|--------------|-------|------------------------------------|------------------|
| 60 | Gastro/Urology | Flexible Stone Dislodger | 876.4680 | II | FGO | 3 | S | Y |
| 61 | Gastro/Urology | Metal Stone Dislodger | 876.4680 | II | FFL | 3 | S | Y |
| 62 | Gastro/Urology | Needle Holder | 876.4730 | I | FHQ | 1 | C | Y |
| 63 | Gastro/Urology | Nonelectrical Snare | 876.4730 | I | FGX | 1 | S | Y |
| 64 | Gastro/Urology | Urological Catheter | 876.5130 | II | KOD | 2 | S | N |
| 65 | Gastro/Urology | Single Needle Dialysis Set | 876.5540 | II | LBW, FIE | 3 | C | N |
| 66 | Gastro/Urology | Hemodialysis Blood Circuit Accessories | 876.5820 | II | KOC | 2 | S | N |
| 67 | Gastro/Urology | Single Needle Dialysis Set | 876.5820 | II | FIF | 3 | C | N |
| 68 | GE/U | Hemorrhoidal Ligator | 876.4400 | II | FHN | 2 | C | N |
| 69 | General Hospital | Implanted, Programmable Infusion Pump | post-amendment | III | LKK | 3 | C | N |
| 70 | General Hospital | Needle Destruction Device | post-amendment | III | MTV | 1 | N | N |
| 71 | General Hospital | Nonpowered Flotation Therapy Mattress | 880.5150 | I | IKY | 2 | N | Y |
| 72 | General Hospital | Non-AC-Powered Patient Lift | 880.5510 | I | FSA | 2 | N | Y |
| 73 | General Hospital | Alternating Pressure Air Flotation Mattress | 880.5550 | II | FNM | 1 | N | Y |
| 74 | General Hospital | Temperature Regulated Water Mattress | 880.5560 | I | FOH | 2 | N | Y |
| 75 | General Hospital | Hypodermic Single Lumen Needle | 880.5570 | II | FMI | 3 | C | N |
| 76 | General Hospital | Piston Syringe | 880.5860 | II | FMF | 3 | C | N |
| 77 | General Hospital | Mattress Cover (Medical Purposes) | 880.6190 | I | FMW | 2 | N | Y |
| 78 | General Hospital | Disposable Medical Scissors | 880.6820 | I | JOK | 1 | N | Y |
| 79 | General Hospital | Irrigating Syringe | 880.6960 | I | KYZ, KYY | 1 | C | Y |
| 80 | Infection Control | Surgical Gowns | 878.4040 | II | FYA | 1 | C | N |
| 81 | Lab | Blood Lancet | 878.4800 | I | FMK | 1 | C | Y |
| 82 | Neuro | Clip Forming/Cutting Instrument, | 882.4190 | I | HBS | 3* | C | Y |
| 83 | Neuro | Drills, Burrs, Trephines, and Accessories (Manual) | 882.4300 | II | HBG | 3* | C | N |
| 84 | Neuro | Drills, Burrs, Trephines, and Accessories (Compound, Powered) | 882.4305 | II | HBF | 3* | C | N |
| 85 | Neuro | Drills, Burrs, Trephines, and Accessories (Simple, Powered) | 882.4310 | II | HBE | 3* | C | N |
| 86 | OB/GYN | Oocyte Aspiration Needle | Unclassified | II | MHK | 3 | C | N |
| 87 | OB/GYN | Laparoscope Accessories | 884.1720 | I | HET | 2 | C | Y |