

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
210	Surgery	Ac-Powered Motor	878.4820	I	GEY	2	C	Y
211	Surgery	Bit	878.4820	I	GFG	1	C	Y
212	Surgery	Bur	878.4820	I	GFF, GEY	1	C	Y
213	Surgery	Cardiovascular Surgical Saw Blade	878.4820	I	DWH	1	C	Y
214	Surgery	Chisel (Osteotome)	878.4820	I	KDG	1	C	Y
215	Surgery	Dermatome	878.4820	I	GFD	1	C	Y
216	Surgery	Electrically Powered Saw	878.4820	I	DWI	2	C	Y
217	Surgery	Pneumatic Powered Motor	878.4820	I	GET	2	C	Y
218	Surgery	Pneumatically Powered Saw	878.4820	I	KFK	2	C	Y
219	Surgery	Powered Saw and Accessories	878.4820	I	HAB	2	C	Y
220	Surgery	Saw Blade	878.4820	I	GFA	1	C	Y
221	Surgery	Nonpneumatic Tourniquet	878.5900	I	GAX	1	N	Y
222	Surgery	Pneumatic Tourniquet	878.5910	I	KCY	1	N	Y
223	Surgery	Endoscopic Staplers	888.4540	I	HXJ	2	C	Y
224	Surgery	Trocar	876.1500 870.1390	II	GCJ, DRC	3	C	N
225	Surgery	Surgical Cutting Accessories	878.4800 874.4420	I	GDZ, GDX, GES, KBQ, KAS	2	C	Y
226	Surgery	Electrosurgical Electrodes/ Handles/Pencils	876.4300 878.4400	II	HAM, GEI, FAS	2	C	N
227	Surgery	Scissor Tips	878.4800 884.4520 874.4420	I	LRW, HDK, HDJ, JZB, KBD	2	C	Y
228	Surgery	Laser Fiber Delivery Systems	878.4810 874.4500 886.4390 884.4550 886.4690	II	GEX, EWG, LLW, HQF, HHR, HQB	1	C	N

<sup>1</sup> N means no.

<sup>2</sup> Y means yes.

† Indicates a change since last publication.

Dated: June 20, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2003D-0236]**

**Draft "Guidance for Industry: Revised  
Recommendations for Donor and  
Product Management Based on  
Screening Tests for Syphilis;"  
Availability**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis" dated June 2003. The draft guidance document provides recommendations for testing donors of blood and blood components for syphilis, and for recommended actions based on those test results. The