

## PROGRAM MEMORANDUM (PM)

PM No.	Title	Issue date	Effective date
AB-03-030 .....	Clinical Laboratory Edit Update .....	02/28/03	04/01/03

**Addendum VI—Categorization of Food and Drug Administration-Allowed Investigational Device Exemptions**

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. Also, under the new categorization process to assist CMS, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories.) Category A refers to experimental/investigational device exemptions, and Category B refers to nonexperimental/investigational device exemptions. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number and category (A or B) for the first quarter, January through March 2003.

**Investigational Device Exemption Numbers, 1st Quarter 2003**

**IDE/Category**

G000247 B  
G003004 B  
G010216 B  
G020225 B  
G020231 B  
G020240 A  
G020244 B  
G020247 B  
G020248 B  
G020262 B  
G020279 B  
G020299 B  
G020301 B  
G020308 B  
G020310 B  
G020311 B  
G020314 B  
G020315 B  
G020317 B  
G020318 B  
G020319 B  
G020320 B  
G020324 B  
G030003 A  
G030004 B  
G030006 B  
G030012 B  
G030013 B

G030014 B  
G030016 B  
G030018 B  
G030019 B  
G030020 B  
G030021 B  
G030023 B  
G030024 B  
G030025 B  
G030028 B  
G030030 B  
G030033 B  
G030035 B  
G030036 B  
G030037 B  
G030041 B  
G030043 A  
G030048 B  
G030049 B  
G030052 B  
G030053 B

**Addendum VII—Approval Numbers for Collections of Information**

Below we list all approval numbers for collections of information in the referenced sections of CMS regulations in title 42 and title 45, subchapter C, of the Code of Federal Regulations, which have been approved by the Office of Management and Budget:

OMB control nos.	Approved CFR sections in title 42 and title 45
0938-0008 .....	414.40, 424.32, 424.44
0938-0022 .....	413.20, 413.24, 413.106
0938-0023 .....	424.103
0938-0025 .....	406.28, 407.27
0938-0027 .....	486.100-486.110
0938-0034 .....	405.821
0938-0035 .....	407.40
0938-0037 .....	413.20, 413.24
0938-0041 .....	408.6
0938-0042 .....	410.40, 424.124
0938-0045 .....	405.711
0938-0046 .....	405.2133
0938-0050 .....	413.20, 413.24
0938-0062 .....	431.151, 435.1009, 440.250, 440.220, 442.1, 442.10-442.16, 442.30, 442.40, 442.42, 442.100-442.119, 483.400-483.480, 488.332, 488.400, 498.3-498.5
0938-0065 .....	485.701-485.729
0938-0074 .....	491.1-491.11
0938-0080 .....	406.13
0938-0086 .....	420.200-420.206, 455.100-455.106
0938-0101 .....	430.30
0938-0102 .....	413.20, 413.24
0938-0107 .....	413.20, 413.24
0938-0146 .....	431.800-431.865
0938-0147 .....	431.800-431.865
0938-0151 .....	493.1-493.2001
0938-0155 .....	405.2470
0938-0170 .....	493.1269-493.1285
0938-0193 .....	430.10-430.20, 440.167
0938-0202 .....	413.17, 413.20
0938-0214 .....	411.25, 489.2, 489.20
0938-0236 .....	413.20, 413.24
0938-0242 .....	416.44, 418.100, 482.41, 483.270, 483.470
0938-0245 .....	407.10, 407.11