

NATIONAL COVERAGE DECISIONS—Continued

[April 2003 Through June 2003]

CIM section	Title	Issue date	Effective date
50–36	PET for Myocardial Perfusion of the Heart Using Ammonia N–13	06/20/03	10/01/03

PM No.	Title	Issue date	Effective date
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Program Memorandum (PM)

AB–03–084	Changes to the Laboratory NCD Edit Software For 07/03 (Blood Counts, Blood Glucose Testing, HIV Testing).	06/06/03	07/01/03
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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 (FDA) assigns each device with an FDA-approved investigational device exemption (IDE) 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 second quarter, April through June 2003.

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 2ND QUARTER 2003

IDE	Category
G010175	B
G010354	B
G020083	B
G020115	A
G020230	B
G020231	B
G020244	B
G020273	B
G020307	B

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 2ND QUARTER 2003—Continued

IDE	Category
G020319	B
G020323	B
G030001	B
G030007	B
G030034	B
G030044	B
G030045	B
G030051	B
G030054	B
G030055	B
G030056	B
G030058	B
G030061	B
G030062	B
G030063	B
G030064	B
G030065	B
G030073	B
G030074	B
G030075	B
G030078	B
G030080	B
G030082	B
G030088	B
G030089	B
G030090	B
G030091	B
G030095	B
G030096	B
G030097	B

INVESTIGATIONAL DEVICE EXEMPTION NUMBERS, 2ND QUARTER 2003—Continued

IDE	Category
G030101	B
G030103	B
G030104	B
G030105	A
G030106	B
G030108	B
G030109	B
G030110	B
G030113	B
G030114	B
G030115	B
G030117	B
G030118	B
G030120	B
G030122	B
G030124	B
G030126	B
G030128	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; Title 45, Subchapter C; and Title 20 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, title 45, and title 20 (note: sections in title 45 are preceded by "45 CFR," and sections in title 20 are preceded by "20 CFR")
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	407.4.
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	406.7, 406.13.
0938–0086	420.200–420.206 and 455.100–455.106.