K132235

510(k) Summary

Date of Summary: October 1, 2013

Product Name IMDx *C. difficile* for Abbott *m*2000

Sponsor
Intelligent Medical Devices, Inc.
19 Blackstone Street
Cambridge, MA 02139

OCT 11 2013

Correspondent
MDC Associates, LLC
Fran White, Regulatory Consultant
180 Cabot Street
Beverly, MA 01915

Device Identification

Trade or Proprietary Name:	IMDx *C. difficile* for Abbott *m*2000
Common or Usual Name:	*C. difficile* nucleic acid amplification test assay
Product Code:	OZN
Regulation Section:	21 CFR 866.3130
Product Classification:	Class II

Intended Use

The IMDx C. *difficile* for Abbott *m*2000 assay is an *in vitro* diagnostic assay that uses real-time polymerase chain reaction (PCR) amplification for the qualitative detection of nucleic acids encoding the toxin A gene (*tcdA*) and toxin B gene (*tcdB*) sequences of toxigenic strains of *Clostridium difficile* in human liquid or soft stool specimens collected from patients suspected of having symptoms of *Clostridium difficile* infection.

The assay is intended to be performed on the Abbott *m*2000 System (which comprises the Abbott *m*2000*sp* and *m*2000*rt* instruments) and is indicated for use as an aid in the diagnosis of *Clostridium difficile* infection. The test is intended to be used directly on liquid or soft stool specimens (unpreserved stool, or stool preserved in Cary Blair transport medium). Negative results do not preclude toxigenic *C. difficile* infection and should not be used as the sole basis for treatment or other patient management decisions. The IMDx *C. difficile* for Abbott m2000 assay is intended for professional use. The device is not intended for point-of-care use.

Device Description

The IMDx *C. difficile* for Abbott *m*2000 assay uses PCR to generate amplified product from the *tcdA* and *tcdB/tcdBv* genes in toxigenic *C. difficile* DNA in clinical specimens. The presence of a toxigenic *C. difficile* target sequence is indicated by the fluorescent signal generated through the use of fluorescently labeled oligonucleotide probes on the Abbott *m*2000*rt* instrument. The probes do not generate a signal unless they are specifically bound to the amplified product. The amplification cycle at which fluorescent signal is detected by the Abbott *m*2000*rt* is inversely proportional to the toxigenic *C. difficile* DNA target concentration present in the original specimen. A bacterial species unrelated to toxigenic *C. difficile* is introduced into each specimen during sample preparation to serve as a process control. The process control bacteria are lysed simultaneously with toxigenic *C. difficile* in the specimen,

and amplified in the same reaction as the *C. difficile* targets using PCR, and serve to demonstrate that the entire assay process has proceeded correctly for each specimen.

Substantial Equivalency

IMDx *C. difficile* for Abbott *m*2000 is substantially equivalent to theQuidel AmpliVue™ C. difficile assay (K123355). Table 1 compares the characteristics of the IMDx *C. difficile* assay (New Device) and the Quidel Amplivue C. difficile assay(Predicate Device).

Table 1. Substantial Equivalence

Similarities		
Characteristic	**Predicate Device Quidel Amplivue C. difficile assay**	**IMDx *C. difficile* for Abbott *m*2000 Assay**
510(k)	K123355	K132235
Regulation	866.3130	866.3130
Product Code	OZN	OZN
Device Class	Class II	Class II
Intended use	The AmpliVue™ C. difficile Assay is an in vitro diagnostic test for the direct, qualitative detection of the *Clostridium difficile* Toxin A gene (*tcdA*) in unformed stool specimens of patients suspected of having *Clostridium difficile*-associated disease (CDAD). The AmpliVue™ C. difficile Assay is intended for use as an aid in diagnosis of CDAD. The assay utilizes helicase-dependlent amplification (HDA) for the amplification of a highly conserved fragment of the Toxin A gene sequence and a self-contained disposable amplicon detection device that allows for manual evaluation of assay results.	The IMDx C. *difficile* for Abbott *m*2000 assay is an *in vitro* diagnostic assay that uses real-time polymerase chain reaction (PCR) amplification for the qualitative detection of nucleic acids encoding the toxin A gene (*tcdA*) and toxin B gene (*tcdB*) sequences of toxigenic strains of *Clostridium difficile* in human liquid or soft stool specimens collected from patients suspected of having symptoms of *Clostridium difficile* infection. The assay is intended to be performed on the Abbott *m*2000 System (which comprises the Abbott *m*2000*sp* and *m*2000*rt* instruments) and is indicated for use as an aid in the diagnosis of *Clostridium difficile* infection. The test is intended to be used directly on liquid or soft stool specimens (unpreserved stool, or stool preserved in Cary Blair transport medium). Negative results do not preclude toxigenic *C. difficile* infection and should not be used as the sole basis for treatment or other patient management decisions. The IMDx *C. difficile* for Abbott m2000 assay is intended for professional use. The device is not intended for point-of-care use.
Sample type	Unformed stool	Soft or liquid stool (unpreserved stool, or stool preserved in Cary Blair transport medium).
Test Principle	Nucleic acid amplification	Real-time PCR DNA amplification
Analyte	Toxin A gene (*tcdA*)	Toxin A gene (*tcdA*) Toxin B genes (*tcdB* and *tcdBv*)
Controls	Process Control included in the kit Positive and Negative Controls not included in kit; separate control kit available for sale	Positive Control, Negative Control and Process Control included in the kit

Differences		
Characteristic	**Predicate Device Quidel Amplivue C. difficile assay**	**IMDx *C. difficile* for Abbott *m*2000 Assay**
Instrument	Self-contained, disposable cassette with an amplicon cartridge and detection chamber	Assay uses the Abbott *m*2000 System for amplification and detection
Extraction Method	Manual	Automated on the Abbott *m*2000*sp*

These differences do not affect substantial equivalence of the IMDx *C. difficile* for Abbott *m*2000 and Quidel Amplivue C. difficile assays. Both assays detect *C. difficile* nucleic acids from soft or liquid unformed stool specimens and have comparable intended uses. The differences noted above do not impact the intended use and do not raise questions as to the safety and effectiveness of the test (new) device.

Performance Characteristics

Analytical Performance

Precision/Reproducibility:
Assay precision was measured in four independent studies: within laboratory repeatability, instrument-to-instrument repeatability, lot-to-lot repeatability, and site to site reproducibility using a seven-membered panel consisting of two *C. difficile* strains at concentrations representing a positive specimen (2-3X LoD), a low positive specimen (1X LoD), a high negative specimen (0.05X LoD), and a negative specimen.

Table 2. Summary of % Agreement for Precision Studies.

	Panel Member	**Reproducibility**	**Lot-to-Lot**	***m*2000*sp* to *m*2000*sp***	***m*2000*rt* to *m*2000*rt***	**Repeatability**	**Overall**
***C. difficile* 1470 *tcdB*-variant (ATCC 43598)**	High Negative	86/106 (81.1%)	15/18 (83.3%)	17/18 (94.4%)	16/18 (88.9%)	61/72 (84.7%)	195/232 (84.1%)
	Low Positive	107/107 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	71/72 (100.0%)	232/233 (99.6%)
	Positive	108/108 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	72/72 (100.0%)	234/234 (100.0%)
***C. difficile* NAP-1 (ATCC BAA-1870)**	High Negative	92/106 (86.8%)	12/17 (70.6%)	12/18 (66.7%)	13/18 (72.2%)	57/70 (81.4%)	186/229 (81.2%)
	Low Positive	106/107 (99.1%)	18/18 (100.0%)	17/17 (100.0%)	18/18 (100.0%)	70/71 (98.6%)	229/231 (99.1%)
	Positive	110/110 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	72/72 (100.0%)	236/236 (100.0%)
	Negative	105/105 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	18/18 (100.0%)	72/72 (100.0%)	231/231 (100.0%)

Analytical Sensitivity (Limit of Detection)
The LoD is defined as the toxigenic *C. difficile* bacterial titer (CFU/mL) detected with a probability of 95% or greater. Three strains of *C. difficile* were used to determine the assay LoD for unpreserved stool specimens and stool specimens preserved in Cary Blair transport media. The results, representative of the analytical sensitivity of the IMDx *C. difficile* for Abbott *m*2000 assay, are summarized in Table 3.

Table 3. Limit of Detection.

Strain	LoD Unpreserved Stool	LoD Cary-Blair Preserved Stool
C. difficile ATCC 43255 Strain: VPI10463 (toxinotype 0)	337 CFU/mL	463 CFU/mL
C. difficile ATCC 43598 Strain: 1470 (*tcdB*-variant)	256 CFU/mL	861 CFU/mL
C. difficile ATCC BAA-1870 Strain: 4118 (BI/NAP1/027)	67 CFU/mL	134 CFU/mL

Analytical Reactivity

A total of 31 different toxigenic *C. difficile* strains were tested to determine if they were detected by the IMDx *C. difficile* for Abbott *m*2000 assay. Strains were tested at a concentration of approximately 2-3X LoD, and were run in triplicate. Strains were considered to be detected if all 3 replicates were detected. All strains were detected.

Cross Reactivity & Microbial Interference

The IMDx *C. difficile* for Abbott *m*2000 assay was evaluated for potential cross reactivity and/or interference using a panel of 120 viruses and microorganisms (see Table 4). Bacteria were tested at a concentration of $\geq 1 \times 10^6$ CFU/mL, and viruses at a concentration of $\geq 1 \times 10^5$ $TCID_{50}$/mL. None of the organisms tested were found to cross-react or interfere with the IMDx *C. difficile* for Abbott *m*2000 assay.

Table 4. Cross Reactivity and Microbial Interference.

Organism	Strain ID	Organism	Strain ID
Abiotrophia defectiva	ATCC 49176	*Enterococcus faecalis vanB*	ATCC 51299
Acinetobacter baumannii	ATCC19606	*Enterococcus faecium vanA*	ATCC 700221
Acinetobacter lwoffii	ATCC17925	*Enterococcus gallinarum vanC*	ATCC 49573
Adenovirus (Type 40)	ZMC 0810084CF	*Enterococcus hirae*	ATCC 8043
Aeromonas hydrophila	ZMC 0601715	*Enterococcus raffinosus*	ATCC 49427
Alcaligenes faecalis subsp. faecalis	ATCC 15554	Enterovirus (Type 71)	ZMC 0810047CF
Anaerococcus tetradius	ATCC 35098	*Escherichia coli*	ATCC 23511
Bacillus cereus	ATCC 11778	*Escherichia coli* O157	ZMC 0801622
Bacillus cereus	ATCC 13472	*Escherichia fergusonii*	ATCC 35469
Bacteroides caccae	ATCC 43185	*Escherichia hermannii*	ATCC 33650
Bacteroides stercoris	ATCC 43183	*Fusobacterium varium*	ATCC 8501
Bifidobacterium adolescentis	ATCC 15703	*Gardnerella vaginalis*	ATCC 14019
Campylobacter coli	ATCC 43479	*Gemella morbillorum*	ATCC 27824
Campylobacter jejuni subsp *jejuni*	ATCC 33292	*Hafnia alvei*	ATCC 13337
Candida albicans	ATCC 10231	*Helicobacter pylori*	ZMC 0601486; Z40
Candida catenulata	ATCC 10565	Homo sapiens	ATCC MGC-15492
Cedecea davisae	ATCC 33431	*Klebsiella oxytoca*	ATCC 33496
Chlamydia trachomatis	ZMC D-UW3; Z054	*Klebsiella pneumoniae* subsp. *pneumoniae*	ATCC 13883
Citrobacter amalonaticus	ATCC 25405	*Lactobacillus acidophilus*	ZMC 0601540

Organism	Strain ID	Organism	Strain ID
Citrobacter freundii	ATCC 8090	*Lactobacillus reuteri*	ATCC 23272
Citrobacter koseri	ZMC 0601745	*Lactococcus lactis* subsp. *lactis*	ATCC 11454
Citrobacter sedlakii	ATCC 51115	*Leminorela grimontii*	ATCC 33999
Clostridium beijerinckii	ATCC 8260	*Listeria grayi*	ATCC 19120
Clostridium bifermentans	ATCC 638	*Listeria innocua*	ATCC 33090
Clostridium bolteae	ATCC BAA-613	*Listeria monocytogenes*	ZMC 0801543
Clostridium butyricum	ATCC 19398	Norovirus	ZMC 0810087CF
Clostridium chauvoei	ATCC 11957	*Peptoniphilus asaccharolyticus*	ATCC 14963
Clostridium difficile (non-toxigenic)	ATCC 43593	*Peptostreptococcus anaerobius*	ATCC 27337
Clostridium difficile (non-toxigenic)	ATCC 43601	*Plesiomonas shigelloides*	ATCC 14029
Clostridium fallax	ATCC 19400	*Porphyromonas asaccharolytica*	ATCC 25260
Clostridium haemolyticum	ATCC 9656	*Prevotella melaninogenica*	ATCC 25845
Clostridium histolyticum	ATCC 19401	*Proteus mirabilis*	ATCC 25933
Clostridium innocuum	ATCC 14501	*Proteus penneri*	ZMC 0601589
Clostridium nexile	ATCC 27757	*Providencia alcalifaciens*	ATCC 9886
Clostridium novyi	ATCC 19402	*Providencia rettgeri*	ATCC 9250
Clostridium orbiscindens	ATCC 49531	*Providencia stuartii*	ATCC 33672
Clostridium paraputrificum	ATCC 25780	*Pseudomonas aeruginosa*	ATCC 35554
Clostridium perfringens	ZMC 0601585	*Pseudomonas putida*	ZMC 0601722
Clostridium ramosum	ATCC 25582	Rotavirus	ZMC MA-104
Clostridium scindens	ATCC 35704	*Ruminococcus bromii*	ATCC 27255
Clostridium sordellii	ATCC 9714	*Salmonella choleraesuis* subsp. choleraesuis	ATCC 7001
Clostridium sphenoides	ATCC 19403	*Salmonella enterica* subsp. *enterica*	ATCC 14028
Clostridium spiroforme	ATCC 29900	*Salmonella enterica* subsp. *arizonae*	ATCC 13314
Clostridium sporogenes	ATCC 15579	*Serratia liquefaciens*	ATCC 27592
Clostridium symbiosum	ATCC 14940	*Serratia marcescens*	ATCC 13880
Clostridium tertium	ATCC 14573	*Shigella boydii*	ATCC 9207
Clostridium tetani	ATCC 19406	*Shigella dysenteriae*	ZMC 0601609
Collinsella aerofaciens	ATCC 25986	*Shigella sonnei*	ATCC 29930
Corynebacterium genitalium LSPQ 3583	ATCC 33798	*Staphylococcus aureus*	ZMC 0601675
Coxsackie virus (Type B4)	ZMC 0810075CF	*Staphylococcus epidermidis*	ATCC 14990
Cytomegalovirus (AD-169)	ZMC 0810003CF	*Stenotrophomonas maltophilia*	ATCC 13637
Desulfovibrio piger	ATCC 29098	*Streptococcus agalactiae*	ZMC 0601545
Echovirus (Type 11)	ZMC 0810023CF	*Streptococcus dysgalactiae*	ATCC 43078
Edwardsiella tarda	ATCC 15947	*Streptococcus intermedius*	ATCC 27335
Eggerthella lenta	ATCC 25559	*Streptococcus uberis*	ATCC 19436
Enterobacter aerogenes	ATCC 13048	*Veillonella parvula*	ATCC 10790
Enterobacter cloacae	ATCC 13047	*Vibrio cholerae*	ATCC 25870
Enterococcus casseliflavus	ZMC 0601565	*Vibrio parahaemolyticus*	ATCC 17802
Enterococcus cecorum	ATCC 43198	*Yersinia bercovieri*	ATCC 43970
Enterococcus dispar	ATCC 51266	*Yersinia rohdei*	ATCC 43380

Interfering Substances

The IMDx *C. difficile* for Abbott *m*2000 assay was challenged with twenty-three (23) substances that may be present in stool specimens. The substances included: anti-fungal/anti-itch vaginal cream, suppositories, anti-hemorrhoid creams/ointments, antacids, enemas, condoms with spermicidal lubricant, anti-diarrheal medication, laxatives, antibiotics (oral and topical), non-steroidal anti-inflammatory medications, moist towelettes, fecal components (e.g., blood, mucus, fecal fats), and MRI contrast agent. No assay interference was observed for any of the substances.

Target Carryover Study

Five assay runs were performed with alternating high positive and negative samples. A single cross-contamination carryover event was observed in one of the five runs, generating a carryover rate of 0.4% (1/235).

Clinical Performance Characteristics

The performance of the IMDx *C. difficile* for Abbott *m*2000 assay was evaluated at seven (7) geographically diverse locations within the United States from 2011 to 2013. A total of 1,565 (1186 unpreserved stool, 379 preserved stool) specimens were included in the final data set and analyzed for product performance as compared to results obtained from Bartels® Cytotoxicity Assay for *Clostridium difficile* Toxin (Trinity Biotech, Carlsbad, CA [Distributed by Diagnostic Hybrids, Athens, OH]).

Table 5. Clinical Agreement Summary: Unpreserved Stool

		Bartels/Cytotoxin		
		Pos	Neg	Total
IMDx *C.difficile* for Abbott *m*2000	Pos	118	79**	197
	Neg	19*	970	989
	Total	137	1049	1186

		95% CI
Sensitivity	86.1%	(79.4% – 90.9%)
Specificity	92.5%	(90.7% – 93.9%)
Positive Predictive Value	59.9%	(52.9% – 66.5%)
Negative Predictive Value	98.1%	(97.0% – 98.8%)
Prevalence	11.6%	

* 16 samples were sequenced, 13 were resolved as negative and 3 remained discrepant.
** 53 samples were sequenced, 40 were resolved as positive, 9 remained discrepant and 4 had indeterminate results.

Table 6. Clinical Agreement Summary: Stool Preserved in Cary Blair Transport Medium

		Bartels/Cytotoxin		
		Pos	Neg	Total
IMDx *C.difficile* for Abbott *m*2000	Pos	21	23**	44
	Neg	2*	333	335
	Total	23	356	379

		95% CI
Sensitivity	91.3%	(73.2% – 97.6%)
Specificity	93.5%	(90.5% – 95.7%)
Positive Predictive Value	47.7%	(33.8% – 62.1%)
Negative Predictive Value	99.4%	(97.8% – 99.8%)
Prevalence	6.1%	

* 2 samples were sequenced, 1 was resolved as negative and 1 remained discrepant.
** 20 samples were sequenced, 12 were resolved as positive and 8 remained discrepant.

Study Results by age

Subjects ranged in age from <1 to 112 years old. The table below shows the number of subjects by age.

Table 7. Study Population Age and Gender Distribution

Age and Gender Distribution of IMDx *C. difficile* for Abbott *m*2000 Assay Positive Results						
Age Group	**Specimen Type & Gender*** # Positive / # Enrolled (Prevalence [%])					
	Raw/Fresh (Unpreserved Stool)			**Cary-Blair (Preserved Stool)**		
	Male	**Female**	**Total**	**Male**	**Female**	**Total (%)**
Unknown age	0/1 (0.0%)	0/1 (0.0%)	0/5[§] (0.0%)	0/0 (0.0%)	0/0 (0.0%)	0/0 (0.0%)
Infant (<2 yrs)	0/4 (0.0%)	2/2 (100.0%)	2/6 (33.3%)	0/3 (0.0%)	0/0 (0.0%)	0/3 (0.0%)
Child (≥2 to <12 yrs)	1/7 (14.3%)	1/9 (11.1%)	2/16 (12.5%)	2/6 (33.3%)	0/3 (0.0%)	2/9 (22.2%)
Adolescent (≥12 to <18 yrs)	0/8 (0.0%)	1/6 (16.7%)	1/14 (7.1%)	0/2 (0.0%)	0/4 (0.0%)	0/6 (0.0%)
Transitional Adolescent (≥18 to ≤21 yrs)	2/7 (28.6%)	3/15 (20.0%)	5/22 (22.7%)	2/4 (50.0%)	1/8 (12.5%)	3/12 (25.0%)
Adult (>21 to ≤59 yrs)	38/273 (13.9%)	40/297 (13.5%)	78/571[†] (13.7%)	11/82 (13.4%)	8/105 (7.6%)	19/187 (10.2%)
Sr. Adult (> 60 yrs)	47/242 (19.4%)	62/310 (20.0%)	109/552 (19.7%)	9/68 (13.2%)	11/94 (11.7%)	20/162 (12.3%)
Total	**88/542 (16.2%)**	**109/640 (17.0%)**	**197/1,186 (16.6%)**	**24/165 (14.5%)**	**20/214 (9.3%)**	**44/379 (11.6%)**

*Prevalence based on *C. difficile* positives with the IMDx *C. difficile* for Abbott *m*2000 assay.

[§]The gender of three individuals in this age group was not known.

[†]The gender of one individual in this age group was not known.

Conclusions

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

INTELLIGENT MEDICAL DEVICES, INC.
C/O FRAN WHITE
REGULATORY CONSULTANT
MDC ASSOCIATES
180 CABOT STREET
BEVERLY MA 01915

Re: K132235
Trade/Device Name: IMDx *C.difficile* for Abbott *m*2000
Regulation Number: 21 CFR 866.3130
Regulation Name: *C. difficile* Nucleic Acid Amplification Test Assay
Regulatory Class: II
Product Code: OZN, OOI
Dated: July 17, 2013
Received: July 18, 2013

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally A. Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132235

Device Name: IMDx *C. difficile* for Abbott *m*2000

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ribhi Shawar -S
2013.10.10 13:13:41 -04'00'