510(k) Summary

510(k) Number – K131508

Device Name: Vysis D7S486/CEP 7 FISH Probe Kit (List No. 04N78-020)

Purpose of the Submission

The purpose of this 510(k) is to gain clearance to market the Vysis D7S486/CEP 7 FISH Probe Kit (List No. 04N78-020).

Official Correspondent to the File

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SEP 13 2013

Date of Preparation

August 5, 2013

Manufacturer

Abbott Molecular Inc. is the legal manufacturer of the Vysis D7S486/CEP 7 FISH Probe Kit (List No. 04N78-020).

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Intended Use/Indications For Use

The Vysis D7S486/CEP 7 FISH Probe Kit is a device intended for specimen characterization, and detects the LSI D7S486 probe target on chromosome 7q31 and the CEP 7 probe target on chromosome 7p11.1-q11.1 in bone marrow and peripheral blood specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this device for diagnosis, prognosis, monitoring or risk assessment has not been established.

Trade Name

Vysis D7S486/CEP 7 FISH Probe Kit (List No. 04N78-020)

Common Name

Vysis D7S486/CEP 7 Fluorescence In Situ Hybridization (FISH) Probe Kit

Classification

Class II

Regulation Number

21 CFR 864.1870

Product Code

PFG

Predicate Device(s)

81, Immunology; PDO, Vysis EGR1 FISH Probe Kit – SC (Specimen Characterization); 510(k) K123951

Comparison with Predicate Device(s)

Predicate	Device Item Being Compared	Similarities	Differences
For specimen characterization and detection of a specific probe target on a chromosome.	Intended Use	Same	
Specimen characterization and detection of LSI EGR1 probe target on chromosome 5q	Indications for Use		Specimen characterization and detection of LSI D7S486 (7q31) probe target on chromosome 7q and the LSI D7S486 and CEP 7 (7p11.1-q11.1) probe targets on chromosome 7.
Acute myeloid leukemia (AML) patients	Patient Population	Same	In addition myelodysplastic syndrome
Vysis EGR1 FISH Probe Kit – SC (Specimen Characterization)	Device Name		Vysis D7S486/CEP 7 FISH Probe Kit
04N37-001	List Number		04N78-020
PDO	PFG		
LSI EGR1	Probe Target		LSI D7S486 CEP 7
Deletion	Type of atypical FISH signal pattern detected	Same	In addition loss of chromosome

DNA Fluorophore labeled Probes Vysis LSI/WCP Hybridization buffer, DAPI II NP-40 20XSSC	Kit components	Same	
Predicate	**Device Item Being Compared**	**Similarities**	**Differences**
FISH assay method	FISH procedure	Same	
6%	Upper reference limit		4.5% (monosomy 7) 6.5% (loss of 7q)
Fluorescence In Situ Hybridization	Technology	Same	
Bone Marrow	Specimen Type	Same	Addition of Peripheral Blood
Analytical Sensitivity Analytical Specificity Reproducibility	Analytical Performance	Same	
Shortest dated component 24 months 24 months 12 months 36 months 60 months	Shelf Life Kit • Probe • Hybridization buffer • DAPI II • NP-40 • 20X SSC	Same	Probe dating 12 months

Device Description

The Vysis D7S486/CEP 7 FISH Probe Kit is for specimen characterization and detects the LSI D7S486 (7q31) probe target on chromosome 7q31 and CEP 7 probe target chromosome 7p11.1-q11.1 in bone marrow and peripheral blood specimens.

DNA Probe Description

Vysis LSI D7S486 SpectrumOrange/ CEP 7 SpectrumGreen Probes:

The SpectrumOrange labeled LSI D7S486 probe is approximately 308 kb in length (chr7:115983468-115675366; February 2009 Assembly UCSC Human Genome Browser).[1]

The SpectrumGreen labeled CEP 7 probe targets the D7Z1 alpha satellite sequence at the centromere of chromosome 7.

The Vysis D7S486/CEP 7 FISH Probe Kit (List No. 04N78-020) consists of a mixture of two DNA FISH probes and four general reagents sufficient to process 20 assays.

- Vysis LSI D7S486 SpectrumOrange/ CEP 7 SpectrumGreen Probes
- Vysis LSI/WCP Hybridization Buffer
- DAPI II Counterstain
- NP-40
- 20X SSC

Summary and Explanation of the Test

Deletion of chromosome 7q and loss of a complete chromosome 7 (monosomy 7) are recurring abnormalities in several hematologic malignancies. Vance et al[2] demonstrated the Vysis LSI D7S486 SpectrumOrange/CEP 7 SpectrumGreen Probes detected deletion of the LSI D7S486 probe target on chromosome 7q or loss of chromosome 7 (monosomy 7) in a series of bone marrow and blood specimens from untreated acute myeloid leukemia (AML) patients. In the study, 179 bone marrow specimens and 47 peripheral blood specimens were tested. Among the 179 bone marrow specimens tested, 4 bone marrow specimens were atypical for the 1R2G FISH pattern associated with a deletion of the locus specific identifier (LSI) D7S486 probe target on chromosome 7q with a range of 58 to 93% atypical nuclei. Among the 179 bone marrow specimens tested, 5 bone marrow specimens were atypical for the 1R1G FISH pattern associated with monosomy 7 with a range of 70 to 96% atypical nuclei. Among the 47 peripheral blood specimens tested, 1 peripheral blood specimen contained the 1R1G atypical FISH pattern in 11% of nuclei . An additional 3 peripheral blood specimens were atypical for the 1R2G FISH pattern with a range of 37 – 96% atypical nuclei. Cherry et al[3] reported the Vysis LSI D7S486

SpectrumOrange/CEP 7 SpectrumGreen Probes detected 7q- in 3 myelodysplastic syndrome (MDS) patients with a range of 22.5 to 44% atypical bone marrow nuclei and also detected monosomy 7 in 2 patients with 23 and 87.5% atypical nuclei. Tefferi et al[4] described 2 myelofibrosis with myeloid metaplasia (MMM) patients who had 9% and 16% bone marrow nuclei with 7q- (1R2G) atypical signal patterns. A peripheral blood specimen from the MMM patient with 16% atypical bone marrow nuclei had 27% of nuclei with the 1R2G atypical signal pattern. The peripheral blood specimen from the patient with 9% 1R2G bone marrow was determined to be typical. However, the author stated that the percent of atypical nuclei may have been below detection limits in this peripheral blood specimen.

The Vysis D7S486/CEP 7 FISH probe kit uses FISH DNA probe technology to detect the probe target for LSI D7S496 (7q31) on chromosome 7q and the probe target for CEP 7 (7p11.1 – q11.1) on chromosome 7.

Technological Description of the Device

FISH is a technique that allows visualization of specific nucleic acid sequences within a cellular preparation. Specifically, FISH involves precise annealing of a single-stranded, fluorophore-labeled DNA probe to a complementary target sequence. Hybridization of the probe with the cellular DNA site is visible by direct detection using fluorescence microscopy. Interpretation of FISH results should be made utilizing appropriate controls and analytical techniques as well as taking into consideration other clinical and diagnostic test data.[5]

Bone marrow and peripheral blood cell specimens attached to microscope slides using standard cytogenetic procedures are used for this assay. The resulting specimen DNA is denatured to single-stranded form and subsequently allowed to hybridize with the probes of the Vysis D7S486/CEP 7 FISH Probe Kit. Following hybridization, the unbound probe is removed by a series of washes, and the nuclei are counterstained with DAPI II, a DNA-specific stain that fluoresces blue. Hybridization of the Vysis LSI D7S486 SpectrumOrange/CEP 7 SpectrumGreen Probes is viewed using a fluorescence

microscope equipped with appropriate excitation and emission filters, allowing visualization of the orange and green fluorescent signals.

In a cell with typical copy numbers of the Vysis LSI D7S486 SpectrumOrange/CEP 7 SpectrumGreen probe targets, two orange (2R) signals (D7S486) and two green (2G) signals (CEP 7) will be expected.

A 1 orange, 1 green (1R1G) pattern is expected in a cell having only one copy of chromosome 7. A 1 orange, 2 green (1R2G) pattern is expected in a cell with loss of 7q.

Summary of Nonclinical Studies

Analytical Specificity

Analytical specificity is defined as the percentage of signals that hybridize to the correct locus and no other location.[5,6] The analytical specificity of the Vysis LSI D7S486 SpectrumOrange//CEP 7 SpectrumGreen Probes for their respective chromosome target loci was established using metaphase chromosomes prepared from peripheral blood cultures of 4 male and 1 female karyotypically normal specimen slides. The hybridization location of each FISH signal on chromosomes of 100 consecutive metaphase nuclei was evaluated by 1 technologist for a total of 200 target loci per probe.

For each probe, the number of metaphase chromosome FISH signals hybridized to the correct locus and the number of metaphase chromosome FISH signals hybridized to the incorrect locus were enumerated.

For each probe, the specificity was calculated as the number of metaphase chromosome FISH signals hybridized to the correct locus divided by the total number of metaphase chromosome FISH signals hybridized and multiplied by 100 to give a percentage.

The analytical specificity of the Vysis LSI D7S486/CEP 7 FISH Probe Kit was 100%, as shown in Table 1.

Table 1. Analytical Specificity

Probe	Correct Target Locus	No. of Metaphase Chromosome Signals		Specificity (%)	95% Confidence Interval (%)
		Hybridized to the Correct Target Locus	Total Hybridized Signals		
LSI D7S486	7q31	200	200	100	(98,100)
CEP 7	7p11.1-q11.1	200	200	100	(98,100)

Analytical Sensitivity

Analytical sensitivity is defined as the percentage of scoreable interphase nuclei with the expected typical signal pattern. The expected typical interphase signal pattern for the probes in the Vysis D7S486/CEP 7 FISH Probe Kit is 2 orange (2R) and 2 green (2G) signals per nucleus.

The analytical sensitivity of the Vysis LSI D7S486 SpectrumOrange//CEP 7 SpectrumGreen Probes was established using interphase nuclei prepared from 25 bone marrow and 25 peripheral blood specimens that were either karyotypically normal individuals or patients lacking monosomy 7 and loss of 7q. The orange and green signal patterns of nuclei for each of the 25 specimens were evaluated by 2 technologists. Each technologist evaluated 100 nuclei per specimen for a total of 200 nuclei per specimen and 5000 scoreable nuclei for each of the specimen types.

The analytical sensitivity was calculated as the percentage of scoreable interphase nuclei with the expected 2R2G signal pattern.

The Vysis D7S486/CEP 7 FISH Probe Kit has an analytical sensitivity of 98.1% for bone marrow and 98.5% for peripheral blood as shown in Table 2.

Table 2. Analytical Sensitivity

		No. of Interphase Chromosome Signals		Analytical Sensitivity	
Probe	Specimen[a]	With Expected Signal Pattern	Scoreable Nuclei	Point Estimate	95% CI[b]
D7S486	BM[b]	4903	5000	98.1	(97.6,98.4)
D7S486	PB[b]	4923	5000	98.5	(98.1,98.8)

[a] 25 Karyotypically normal specimens for both specimen types.
[b] BM: Bone Marrow; PB: Peripheral Blood; CI: Confidence interval

Verification of Upper Reference Limit

The upper reference limit is defined as the maximum quantity of scoreable interphase nuclei with a specific atypical signal pattern at which a specimen is considered karyotypically normal for that signal pattern. The upper reference limit is expressed in terms of a percentage or the actual number of a specific atypical nuclear FISH signal pattern per the standard number of nuclei tested.

The upper reference limit for monosomy 7 is 4.5% or 9 1R1G patterns per 200 scoreable interphase nuclei, and the upper reference limit for loss of 7q is 6.5% or 13 1R2G patterns per 200 scoreable interphase nuclei. Specimens exceeding 9 1R1G patterns and/or 13 1R2G patterns per 200 scoreable nuclei are considered atypical for monosomy 7 and/or loss of q arm on chromosome 7 with the Vysis D7S486/CEP 7 FISH probe target.

The Vysis D7S486/CEP 7 assay was performed on interphase nuclei from 25 bone marrow and 25 peripheral blood specimens from either karyotypically normal individuals or patients lacking monosomy 7 and loss of 7q. The signal patterns of 200 nuclei for each specimen type were evaluated by each of 2 technologists scoring 100 nuclei per specimen.

Among the 25 karyotypically normal specimens for both peripheral blood and bone marrow, none produced 1R1G and 1R2G signals above the 4.5% and 6.5% upper reference limits.

Reproducibility

Two replicates of the assay were run on 2 high-positive, 2 low-positive, and 2 negative panel members at 3 sites on 5 non-consecutive days for each specimen type. The positive panel members for the site-to-site study were obtained by mixing positive cells with normal cells, for each of the specimen types, to obtain the desired levels of positivity. Results shown in Tables 3 through 6 show the overall agreement with the negative/positive status of the test panel members.

All 3 sites demonstrated 100% agreement with the known status of the negative and high positive panel members for both specimen types and both signal patterns. For the bone marrow specimens, the low positives demonstrated 88% (del(7q)) and 97% (monosomy 7) agreement. For the peripheral blood, the low positives demonstrated 95% (del(7q)) and 93% (monosomy 7) agreement.

Table 3. Overall Agreement, Site-to-Site – For Specimen type BM and signal Del (7q)

	Number			
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Percent Agreement**
Negative	60	0	60	100%
Low Positive	53	7	60	88%
High Positive	60	0	60	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides.

Table 4. Overall Agreement, Site-to-Site – For Specimen type BM and signal Monosomy 7

	Number			
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Percent Agreement**
Negative	60	0	60	100%
Low Positive	58	2	60	97%
High Positive	60	0	60	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides.

Table 5. Overall Agreement, Site-to-Site – For Specimen type PB and signal Del (7q)

	Number			
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Percent Agreement**
Negative	60	0	60	100%
Low Positive	57	3	60	95%
High Positive	60	0	60	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides.

Table 6. Overall Agreement, Site-to-Site – For Specimen type PB and signal Monosomy 7

	Number			
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Percent Agreement**
Negative	60	0	60	100%
Low Positive	56	4	60	93%
High Positive	60	0	60	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides.

The mean and the standard deviation (SD) of the percentage of cells with the 1R2G and 1R1G signal patterns were calculated.

The analysis of variance components for the site-to-site study is shown in Tables 7 through 10.

Table 7. Site-to-Site Analysis of Variance Components – For Specimen type BM and signal Del (7q)

			Within-Day (Comp.)	Between-Day (Comp.)	Between-Site (Comp.)	Total
Sample	**N**	**Mean**	**SD**	**SD**	**SD**	**SD**
Negative 1	30	0.5	0.27	0.32	0.06	0.43
Negative 2	30	0.4	0.38	0.14	0.24	0.47
Low Positive 1	30	10.5	2.11	1.41	1.14	2.78
Low Positive 2	30	10.0	3.19	0.00	2.33	3.95
High Positive 1	30	43.9	6.76	0.00	7.62	10.19
High Positive 2	30	42.0	4.61	0.00	5.44	7.13

Table 8. Site-to-Site Analysis of Variance Components – For Specimen type BM and signal Monosomy 7

			Within-Day (Comp.)	Between-Day (Comp.)	Between-Site (Comp.)	Total
Sample	**N**	**Mean**	**SD**	**SD**	**SD**	**SD**
Negative 1	30	0.5	0.67	0.14	0.49	0.84
Negative 2	30	0.3	0.37	0.00	0.25	0.44
Low Positive 1	30	8.9	2.61	0.00	1.19	2.87
Low Positive 2	30	9.3	2.43	0.00	0.00	2.43
High Positive 1	30	48.3	6.20	1.30	8.06	10.25
High Positive 2	30	43.9	3.78	3.97	4.19	6.90

Table 9. Site-to-Site Analysis of Variance Components – For Specimen type PB and signal Del (7q)

Sample	N	Mean	Within-Day (Comp.) SD	Between-Day (Comp.) SD	Between-Site (Comp.) SD	Total SD
Negative 1	30	0.4	0.53	0.27	0.38	0.71
Negative 2	30	0.4	0.42	0.25	0.00	0.49
Low Positive 1	30	10.4	2.46	0.00	2.03	3.19
Low Positive 2	30	12.5	2.57	0.00	0.38	2.60
High Positive 1	30	42.1	3.26	2.05	5.82	6.98
High Positive 2	30	52.8	4.07	1.82	2.15	4.95

Table 10. Site-to-Site Analysis of Variance Components – For Specimen type PB and signal Monosomy 7

Sample	N	Mean	Within-Day (Comp.) SD	Between-Day (Comp.) SD	Between-Site (Comp.) SD	Total SD
Negative 1	30	0.3	0.65	0.00	0.32	0.72
Negative 2	30	0.4	0.47	0.20	0.25	0.57
Low Positive 1	30	9.1	2.61	0.00	0.55	2.67
Low Positive 2	30	6.9	2.35	0.52	0.27	2.42
High Positive 1	30	44.8	3.77	0.00	5.35	6.55
High Positive 2	30	38.8	3.90	3.17	1.63	5.29

Using the same panel members from the site-to-site study, 4 replicates of the assay were run on 2 high-positive, 2 low-positive, and 2 negative panel members using 3 different lots of probe at a single site for each specimen type. The overall agreement with the known negative/positive status of the test panel members is shown in Tables 11 through 14.

All 3 lots demonstrated 100% agreement with the know status of the negative and high positive panel members for both specimen types and both signal patterns. For the bone marrow specimens, the low positives demonstrated 88% (del(7q)) and 92% (monosomy 7) agreement. For the peripheral blood, the low positives demonstrated 100% (del(7q)) and 96% (monosomy 7) agreement.

Table 11. Overall Agreement, Lot-to-Lot – For Specimen type BM and signal Del (7q)

	Number			Percent
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Agreement (%)**
Negative	24	0	24	100%
Low Positive	21	3	24	88%
High Positive	24	0	24	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides

Table 12. Overall Agreement, Lot-to-Lot – For Specimen type BM and signal Monosomy 7

	Number			Percent
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Agreement (%)**
Negative	24	0	24	100%
Low Positive	22	2	24	92%
High Positive	24	0	24	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides

Table 13. Overall Agreement, Lot-to-Lot – For Specimen type PB and signal Del (7q)

	Number			Percent
Category	**Agree[a]**	**Disagree[b]**	**Total**	**Agreement (%)**
Negative	24	0	24	100%
Low Positive	24	0	24	100%
High Positive	24	0	24	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides

Table 14. Overall Agreement, Lot-to-Lot – For Specimen Type PB and signal Monosomy 7

	Number			Percent
Category	Agree[a]	Disagree[b]	Total	Agreement (%)
Negative	24	0	24	100%
Low Positive	23	1	24	96%
High Positive	24	0	24	100%

[a] Agree is number of concordant slides.
[b] Disagree is number of discordant slides

The analysis of variance components for the lot-to-lot study is shown in Tables 15 through 18.

Table 15. Lot-to-Lot Analysis of Variance Components – For Specimen type BM and signal Del (7q)

			Within-Lot (Comp)	Between-Lot (Comp)	Total
Sample	N	Mean	SD	SD	SD
Negative 1	12	0.1	0.22	0.06	0.23
Negative 2	12	0.2	0.28	0.00	0.28
Low Positive 1	12	8.7	2.31	1.63	2.82
Low Positive 2	12	11.3	1.58	0.00	1.58
High Positive 1	12	47.8	5.65	2.49	6.17
High Positive 2	12	48.9	3.53	2.66	4.42

Table 16. Lot-to-Lot Analysis of Variance Components – For Specimen type BM and signal Monosomy 7

			Within-Lot (Comp)	Between-Lot (Comp)	Total
Sample	**N**	**Mean**	**SD**	**SD**	**SD**
Negative 1	12	0.1	0.22	0.06	0.23
Negative 2	12	0.0	0.14	0.00	0.14
Low Positive 1	12	6.8	2.58	0.88	2.73
Low Positive 2	12	8.1	1.16	0.00	1.16
High Positive 1	12	43.9	6.55	4.86	8.16
High Positive 2	12	38.5	4.03	3.71	5.48

Table 17. Lot-to-Lot Analysis of Variance Components – For Specimen type PB and signal Del (7q)

			Within-Lot (Comp)	Between-Lot (Comp)	Total
Sample	**N**	**Mean**	**SD**	**SD**	**SD**
Negative 1	12	0.1	0.22	0.06	0.23
Negative 2	12	0.1	0.20	0.00	0.20
Low Positive 1	12	11.6	2.14	0.98	2.35
Low Positive 2	12	11.0	1.99	0.00	1.99
High Positive 1	12	46.5	2.47	1.52	2.89
High Positive 2	12	58.1	3.38	0.00	3.38

Table 18. Lot-to-Lot Analysis of Variance Components – For Specimen type PB and signal Monosomy 7

			Within-Lot (Comp)	Between-Lot (Comp)	Total
Sample	**N**	**Mean**	**SD**	**SD**	**SD**
Negative 1	12	0.0	0.00	0.00	0.00
Negative 2	12	0.0	0.14	0.00	0.14
Low Positive 1	12	9.1	2.05	1.76	2.70
Low Positive 2	12	5.7	1.22	0.00	1.22
High Positive 1	12	37.1	2.87	0.90	3.01
High Positive 2	12	32.0	3.42	1.69	3.81

Summary of Results from Cited Published Literature

Cited published literature may discuss device uses that have not been approved or cleared by FDA.

Data from supporting literature

Literature Reference	Population Studied	Number and Type of Specimens	Device Used	Observed D7S486/CEP 7 Results
Vance et al[1]	AML[a]	179 bone marrow and 47 blood specimens[b]	Vysis LSI D7S486/CEP 7 probes	Overall 7q- (1R2G signal pattern) was detected in 4/179 bone marrow specimens and 3/47 peripheral blood specimens. Overall monosomy 7 (1R1G signal pattern) was detected in 5/179 bone marrow specimens and 1/47 peripheral blood specimens.
Cherry et al[2]	MDS[a]	48 bone marrow specimens	Vysis LSI D7S486/CEP 7 probes	Overall 7q- (1R2G signal pattern) was detected in 3/48 bone marrow specimens. Overall monosomy 7 (1R1G signal pattern) was detected in 2/48 bone marrow specimens.
Tefferi et al[3]	MMM[a]	42 bone marrow and peripheral blood specimens	Vysis LSI D7S486/CEP 7 probes	Overall 7q- (1R2G signal pattern) was detected in 2/42 bone marrow specimens and 1/42 peripheral blood specimens.

[a] AML: acute myeloid leukemia; MDS: myelodysplastic syndrome; MMM: myelofibrosis with myeloid metaplasia

[b] Based on unpublished data.

BIBLIOGRAPHY

1. Genome Bioinformatics Group of UC Santa Cruz. The UCSC Genome Browser. © The Regents of the University of California. Available at: http://genome.ucsc.edu/cgi-bin/hgGateway?hgsid=185806115&clade=mammal&org=Human&db=hg18. Accessed [April 30, 2013].

2. Vance GH, Kim H, Hicks GA, et al. Utility of interphase FISH to Stratify Patients into Cytogenetic Risk Categories at Diagnosis of AML in an Eastern Cooperative Oncology Group (ECOG) Clinical Ttrial (E1900). *Leuk Res.* 2007;31:605-09.

3. Cherry A, Brockman S, Paternoster, S et al. Comparison of interphase FISH and metaphse cytogenetics to study myelodysplastic syndrome: an Eastern Cooperative Oncology Group (ECOG) study. *Leuk Res.* 2003;27:1085–1090.

4. Tefferi A, Meyer R, Wyatt W, et al. Comparison of peripheral blood interphase cytogenetics with bone marrow karyotype analysis in myelofibrosis with myeloid metaplasia. *Br J Haematol.* 2001;115:316-319.

5. Wiktor AE, Van Dyke DL, Stupca PJ et al. Preclinical validation of fluorescence in situ hybridization assays for clinical practice. *Genet Med.* 2006;8:16-23.

6. AMERICAN COLLEGE OF MEDICAL GENETICS (ACMG). Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 13, 2013

ABBOTT MOLECULAR, INC.
NANCY W. BENGTSON
MANAGER, GLOBAL REGULATORY AFFAIRS
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Re: K131508
Trade/Device Name: Vysis D7S486/CEP 7 FISH Probe Kit
Regulation Number: 21 CFR 864.1870
Regulation Name: Early growth response 1 (EGFR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization
Regulatory Class: II
Product Code: PFG
Dated: August 13, 2013
Received: August 14, 2013

Dear Dr. Bengtson:

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,

Reena Philip -S

for

Maria M. Chan, Ph.D.
Director, Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131508

Device Name: Vysis D7S486/CEP 7 FISH Probe Kit

Indications For Use:

The Vysis D7S486/CEP 7 FISH Probe Kit is a device intended for specimen characterization, and detects the LSI D7S486 probe target on chromosome 7q31 and the CEP 7 probe target on chromosome 7p11.1-q11.1 in bone marrow and peripheral blood specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this device for diagnosis, prognosis, monitoring, or risk assessment has not been established.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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

Donna M. Roscoe -S
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Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)____K131508____