Boston Cell Standards, Inc.
% Gail Radcliffe, President
Radcliffe Consulting, Inc.
23 Fairbanks St
West Boylston, MA 01583

August 15, 2022

Re: K220163
Trade/Device Name: HER2/ER/PR IHControls® - Level H
HER2/ER/PR IHControls® - Level M
HER2/ER/PR IHControls® - Level L
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry Reagents And Kits
Regulatory Class: Class II
Product Code: NJW
Dated: January 10, 2022
Received: January 20, 2022

Dear Gail Radcliffe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics
and Pathology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220163

Device Name
Her2/ER/PR IHControls® - Level H
Her2/ER/PR IHControls® - Level M
Her2/ER/PR IHControls® - Level L

Indications for Use *(Describe)*

HER2/ER/PR IHControls® -Level H
HER2/ER/PR IHControls® -Level H are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® -Level H are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® -Level H are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

HER2/ER/PR IHControls® -Level M
HER2/ER/PR IHControls® -Level M are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® -Level M are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® -Level M are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

HER2/ER/PR IHControls® -Level L
HER2/ER/PR IHControls® -Level L are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® -Level L are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® -Level L are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

5.1 Boston Cell Standards (BCS)

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5.2 Device

Trade Name:

HER2/ER/PR IHControls® - Level H
HER2/ER/PR IHControls® - Level M
HER2/ER/PR IHControls® - Level L

Common name: Control Material, peptide-based controls for HER2, ER, and PR, Immunohistochemistry
Regulation number: 864.1860
Product Code: NJW
Class: 2

5.3 Predicate Device

QCS HER2 Immunocontrols (K023335)

5.4 Intended Use

HER2/ER/PR IHControls® - Level H
HER2/ER/PR IHControls® - Level H are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® - Level H are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® - Level H are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

HER2/ER/PR IHControls® - Level M
HER2/ER/PR IHControls® - Level M are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® - Level M are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® - Level Mare an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

HER2/ER/PR IHControls® - Level L
HER2/ER/PR IHControls® - Level L are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples.

HER2/ER/PR IHControls® - Level L are not intended to be used for scoring HER2, ER, and PR IHC stained slides.

HER2/ER/PR IHControls® - Level L are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.

5.5 Device Description

HER2/ER/PR IHControls® - Level H, HER2/ER/PR IHControls® - Level M and HER2/ER/PR IHControls® - Level L (HER2/ER/PR IHControls®) are immunostaining positive controls for diagnostic immunohistochemistry laboratories. The same immunohistochemical reaction that occurs on a tissue or cellular sample also occurs on the HER2/ER/PR IHControls® microbead. As a result of immunostaining, the microbead bearing the analyte turns the same color as cells expressing the analyte.

HER2/ER/PR IHControls® incorporate assay controls for human epidermal growth factor receptor type II (HER-2), estrogen receptor (ER), and progesterone receptor (PR). The HER2/ER/PR panel includes controls at 3 different analyte concentrations, providing users with an opportunity to select the control with an analyte concentration within the dynamic range of their assay.

HER2/ER/PR IHControls® are provided in a small vial containing enough liquid suspension for at least 100 tests. The user is instructed to pipet a one microliter droplet onto the slide that also bears the patient sample. The droplet is a suspension containing microscopic glass microbeads that are approximately the same size as cells. The microbead surface bears the molecule(s) being measured. Peptides representing the epitopes of all of the major commercial HER2, ER, and PR antibodies used by clinical immunohistochemistry laboratories are incorporated into the products.

HER2/ER/PR IHControls® are comprised of two different microbeads: analyte-coated glass test microbeads (7–8 µm in diameter) and color standard microbeads (4.5 µm in diameter). The latter provide a fixed brown color intensity for use in standardizing stain intensity measurement.

The HER2/ER/PR IHControls® panel is provided at 3 different analyte concentrations. In descending order of concentration, these levels are denoted “H”, “M”, and “L”. These different products allow matching the analyte concentration to the dynamic range of the laboratory’s stain.

Level H (high)	This product includes analytes for HER2, ER, and PR, at approximately 10^6 molecules per microbead.
Level M (medium)	This product includes analytes for HER2, ER, and PR, at approximately 10^5 molecules per microbead.
Level L (low)	This product includes analytes for HER2, ER, and PR, at approximately 10^4 molecules per microbead.

These concentrations are approximate; they are not intended as assayed controls.

Three product levels are provided to allow the user to select a control with the lowest analyte concentration that still produces an easily visible immunostain.

The immunoreactivity pattern for product levels H, M, and L is described in **Table 1**. The table indicates the primary antibodies corresponding with up to 9 separate HER2/ER/PR peptides.

(Some peptides are immunoreactive with more than one primary antibody.) Level H has a narrower range of primary antibody immunoreactivity than levels M and L but the concentrations per microbead are higher. Although any individual primary antibody will be listed as potentially immunoreactive with 2 or more levels, IHC laboratories should use the lowest level that provides for an easily visible stain.

Table 1. HER2/ER/PR IHControls® Immunoreactivity: Levels H, M, and L

Level H (BRLS11)	Level M (BRL2U04)	Level L (BRL2W08)
HER2 CB11	HER2 CB11	HER2 CB11
HER2 4B5	HER2 4B5	HER2 4B5
HercepTest	HercepTest	HercepTest
PR 636	PR 636	PR 636
PR 16	PR 16	PR 16
ER EP1	ER EP1	ER EP1
	ER 1D5/2.123	ER 1D5/2.123
	ER 6F11	ER 6F11
	PR 1294	PR 1294
	PR 1E2	PR 1E2
	ER SP1	ER SP1

Users pipette a droplet onto a microscope slide that also bears a patient's tissue sample. The droplet hardens upon drying, adheres the analyte-coated microbeads to the microscope slide, and is then processed with the patient sample. The hardened droplet is able to pass through dry heat associated with "baking" of slides, organic solvents associated with deparaffinization, boiling associated with antigen retrieval, and repeated rinses associated with immunostaining.

5.6 Principle of Operation

The HER2/ER/PR IHControls® contain analytes that are immunoreactive in IHC stains. They are present on every slide. Therefore, negative staining due to analytic error is readily detectable. Like tissue samples, the HER2/ER/PR IHControls® are formalin-fixed during manufacture. Therefore, test microbeads in the HER2/ER/PR IHControls® products may demonstrate improved immunoreactivity after antigen retrieval.

5.7 Substantial Equivalence

The similarities and differences between Boston Cell Standards HER2/ER/PR IHControls® and the predicate (QCS control slides for HER2 IHC) are outlined in the table below.

Table 2. Comparison of HER2/ER/PR IHControls® Panel to Predicate

Features	HER2/ER/PR IHControls® Panel	Predicate: QCS control slides for HER2 IHC (K023335)
Similarities		
Intended Use	Her2/ER/PR IHControls® -Level H Her2/ER/PR IHControls® -Level H are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples. Her2/ER/PR IHControls® -Level H are not intended to be used for scoring HER2, ER, and PR IHC stained slides. Her2/ER/PR IHControls® -Level H are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device. Her2/ER/PR IHControls® -Level M Her2/ER/PR IHControls® -Level M are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples. Her2/ER/PR IHControls® -Level M are	*QCS HER2 ImmunoControls*, are intended for laboratory use to control semi-quantitative immunohistochemistry using different Her2/neu antibodies. This control ensures that performance of immunohistochemical staining is consistent in one laboratory over time and also aids in correlation with the results of other laboratories.

	not intended to be used for scoring HER2, ER, and PR IHC stained slides. Her2/ER/PR IHControls® -Level M are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device. <u>Her2/ER/PR IHControls® -Level L</u> Her2/ER/PR IHControls® -Level L are peptide based qualitative on-slide controls to monitor the performance of the analytic components (antigen retrieval and immunostaining) of the immunohistochemical (IHC) staining process for certain human epidermal growth factor receptor type II (HER2), estrogen receptor (ER) and progesterone receptor (PR) IHC stains. It is indicated for use with formalin-fixed paraffin-embedded (FFPE) breast tumor samples. Her2/ER/PR IHControls® -Level L are not intended to be used for scoring HER2, ER, and PR IHC stained slides. HER2/ER/PR IHControls® -Level L are an additional control to the run controls specified in the HER2, ER, or PR IHC device labeling and are not intended to replace the controls approved or cleared as part of an IHC device.	
Control configuration	<u>Level H</u> This product includes analytes for HER2, ER, and PR, at approximately 10^6 molecules per microbead. <u>Level M</u> This product includes analytes for HER2, ER, and PR, at approximately 10^5 molecules per microbead. <u>Level L</u> This product includes analytes for	Breast cancer cell lines (MDA-361, MDA-453, MCF-7) for detection of HER2.

	HER2, ER, and PR, at approximately 10^4 molecules per microbead.	
Assay compatibility	Polyclonal and monoclonal IHC stains	Polyclonal and monoclonal IHC stains
Analyte concentration	Three different levels of HER2, ER, PR each at different concentration.	Three different cell lines each expressing unknown concentrations of HER2.
Differences		
Reagents	Formalin-fixed HER2, ER, PR peptide epitopes covalently attached to glass microbeads in a liquid matrix that adhere to a slide.	Formalin-fixed paraffin embedded breast cancer cell lines expressing HER2 protein, mounted on slides.
Slide controls	Controls on every slide, as per regulatory guidelines.	Separate slides for batch control

5.8 Analytical Performance Studies

5.8.1 Specificity

The HER2/ER/PR IHControls® were tested against twenty-six (26) antigenically irrelevant, commonly used primary antibodies, in the context of clinical IHC testing (**Table 3**). Positive tissue controls demonstrated that the antigenically irrelevant tests were operating correctly. No cross-reactivity was detected with the HER2/ER/PR IHControls®. When an appropriate ER, HER2 and PR primary antibody was used for staining, HER2/ER/PR IHControls® demonstrated immunoreactivity.

Table 3. Specificity Testing - List of Primary Antibodies, Targets, and Test Results

	Marker	Organ	Antibody	Tissue Control	IHControls®
1.	Bcl-6	Tonsil	GI191E/A8	Positive	Negative
2.	C4d	Tonsil	SP91	Positive	Negative
3.	CD10	Tonsil	SP67	Positive	Negative
4.	CD138	Tonsil	B-A38	Positive	Negative
5.	CD20	Tonsil	L26	Positive	Negative
6.	CD34	Tonsil	QBEnd/10	Positive	Negative
7.	CD5	Tonsil	SP19	Positive	Negative
8.	CD56	Tonsil	MRQ-42	Positive	Negative
9.	CMV	Placenta	CMV	Positive	Negative
10.	Cyclin D1	Lymphoma	SP4-R	Positive	Negative
11.	Cytokeratin 20	Colon	SP33	Positive	Negative
12.	Cytokeratin 7	Lung	SP52	Positive	Negative
13.	EFGR	Normal Skin	5B7	Positive	Negative
14.	Keratin	Skin	34BE12	Positive	Negative
15.	Ki-67	Tonsil	30-9	Positive	Negative
16.	Mart-1	Melanoma	A103	Positive	Negative
17.	MITF	Melanoma	C5/D5	Positive	Negative
18.	p53	p53	BP53-11	Positive	Negative
19.	p63	Prostate	4A4	Positive	Negative
20.	Pan Keratin	Appendix	AE1/AE3/PCK26	Positive	Negative
21.	Podoplanin	Tonsil	D2-40	Positive	Negative
22.	PSA	Prostate	PSA	Positive	Negative
23.	S100	S100	4C4.9	Positive	Negative
24.	Somatostatin	Pancreas	Somatostatin	Positive	Negative
25.	TAG 72	Colon	B72.3	Positive	Negative
26.	TTF-1	Thyroid	8G7G3/1	Positive	Negative
27.	Breast	Breast ca	ER SP1	Positive	Positive
28.	Breast	Breast ca	HER2 4B5	Positive	Positive
29.	Breast	Breast ca	PR 1E2	Positive	Positive

5.8.2 Shelf Life

The shelf life for each HER2/ER/PR IHControl® level, when stored at 2 – 8° C, was tested in real time over approximately 2 years. **Table 4** summarizes product shelf life.

Table 4. Product Shelf-Life

Product	Shelf Life (days)
Level H (BRLS11)	392
Level M (BRL2U04)	392
Level L (BRL2W08)	392

5.8.3 Reproducibility of Pathologist IHControl® Readouts

Three pathologists evaluated a blinded slide set of 30 stained HER2/ER/PR IHControl® slides.

Ten (10) slides each were stained for HER2, ER, and PR. In each set of ten, 4 were stained with a diluted primary antibody, or no primary antibody, to create weak or absent staining. Overall agreement (**Table 5**) among pathologists for the interpretation of HER2/ER/PR IHControls® was 100%. Pathologists are able to visually interpret HER2/ER/PR IHControls® and reproducibly render Pass or Fail scores.

Table 5. Pathologist Reader Reproducibility

Slide number	Pathologist 1	Pathologist 2	Pathologist 3	Expected Result	Concordance
HER2					
1	P	P	P	P	100%
2	P	P	P	P	100%
3	F	F	F	F	100%
4	P	P	P	P	100%
5	F	F	F	F	100%
6	P	P	P	P	100%
7	F	F	F	F	100%
8	P	P	P	P	100%
9	F	F	F	F	100%
10	P	P	P	P	100%
ER					
11	P	P	P	P	100%
12	P	P	P	P	100%
13	F	F	F	F	100%
14	P	P	P	P	100%
15	F	F	F	F	100%
16	P	P	P	P	100%
17	F	F	F	F	100%
18	P	P	P	P	100%
19	F	F	F	F	100%
20	P	P	P	P	100%
PR					
21	P	P	P	P	100%
22	P	P	P	P	100%
23	F	F	F	F	100%
24	P	P	P	P	100%
25	F	F	F	F	100%
26	P	P	P	P	100%
27	F	F	F	F	100%
28	P	P	P	P	100%
29	F	F	F	F	100%
30	P	P	P	P	100%

5.9 Clinical Performance Studies

The HER2/ER/PR IHControls® were incorporated as on-slide controls for HER2, ER, and/or PR immunostaining at three clinical immunohistochemical laboratories. The laboratories incorporated the HER2/ER/PR IHControls® but otherwise followed their typical method for patient testing. After immunostaining was complete, the laboratories performed an assessment. For each stained slide, the pathologist interpreted both the conventional (tissue) control and the HER2/ER/PR IHControls®, for each of the HER2, ER, and PR stains. The controls (tissue

controls or HER2/ER/PR IHControls®) were scored as either "Pass" or "Fail", depending on whether the control shows that the test passed or failed the quality control check. Percent concordance is reported.

The overall concordance rate is 440 out of 442 tests, or 99.5%, from all 3 clinical trial sites, for ER, PR, and HER2 tests combined (**Table 6**). Individual site concordance was 100%, 99.5%, and 99.1%.

Two discrepancies between tissue controls and HER2/ER/PR IHControls® were due to operator error: (1) use of an incorrect HER2/ER/PR IHControl®, and (2) placement of the HER2/ER/PR IHControls® at the slide edge because the patient sample and tissue (comparator) control left no other place. There was also one site where a histotechnologist did not pipette the HER2/ER/PR IHControls® onto the slide.

Table 6. Data Summary from Five Clinical Sites

Site	Immunostain	Product Tested	# Slides	Concurrence	Deviations
1	ER NCL-L-ER-6F11	**BRL**2U04-001	39	39/39	0
	PR NCL-L-PGR-312	**BRL**S11-001	39	39/39	0
	HER2 BOND Oracle	**BRL**2U04-001	39	39/39	0
2	PR Agilent M3569	**BRL**2U04-001	172*	171/172	1
	HER2 PATHWAY	**BRL**S11-003	42	42/42	0
3	ER CONFIRM	**BRL**2W08-003	37	36/37	1
	PR BOND PA0312	**BRL**S11-001	37	37/37	0
	HER2 PATHWAY	**BRL**S11-001	37	37/37	0

*Slides from two days were deemed uninformative and not counted. This accounts for the difference between 182 slides tested and the denominator in the concurrence column being 172, as there were 5 slides per day that did not generate any data.

The data (**Table 6**) demonstrate that the HER2/ER/PR IHControls® provide an equally accurate assessment of IHC test quality.

6.0 Conclusions from Nonclinical and Clinical Data

The conclusions drawn from the analytical and clinical data demonstrate that the device is safe and effective for its intended use.