FDA U.S. FOOD & DRUG ADMINISTRATION

EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
Procise ADL
DECISION SUMMARY

I Background Information:

A De Novo Number

DEN220023

B Applicant

ProciseDx Inc.

C Proprietary and Established Names

Procise ADL

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QYD	Class II	21 CFR 862.3115 - Anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

De Novo request for evaluation of automatic class III designation for Procise ADL

B Measurand:

Adalimumab (ADL)

C Type of Test:

Quantitative, Time-resolved fluorescence energy transfer immunoassay

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

III Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Procise ADL assay is a time-resolved fluorescence energy transfer immunoassay for the quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, using the ProciseDx Analyzer.

Measurements obtained by this assay can be used to detect adalimumab as an aid in the management of patients with inflammatory bowel diseases (IBD): Crohn's disease and ulcerative colitis being treated with adalimumab. The test is intended for use in a clinical laboratory.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostics use only

D Special Instrument Requirements:

ProciseDx Analyzer

IV Device/System Characteristics:

A Device Description:

Each Procise ADL assay kit includes Procise ADL reagent cartridges, buffer bulbs, and Procise ADL low and high assay controls as follows:

- Twenty pouched Procise ADL cartridges each containing a lyophilized test-specific reagent bead located in the cartridge cap comprised of test-specific conjugates (monoclonal Fab anti-ADL/TNFα complex labeled with acceptor fluorophore and TNFα protein labeled with donor fluorophore)
- Twenty 1.5 mL buffer bulbs
- Two pouched assay ADL Low controls
- Two pouched assay ADL High controls
- Product Insert
- Quick Reference Guide

The Procise ADL assay requires the ProciseDx Analyzer. The ProciseDx Analyzer is designed to detect time-resolved fluorescent signal from both the donor and FRET acceptor emission within the Procise ADL assay.

B Principle of Operation
The Procise ADL assay is a sandwich immunoassay that uses time-resolved fluorescence to detect the presence and quantity of ADL in patient serum specimens. It is a homogenous assay

that uses an energy transfer between a terbium cryptate acceptor fluorophore labeled anti-ADL/TNFα complex Fab' antibody and a terbium cryptate donor fluorophore labeled to TNFα protein. When ADL is present in a sample and tested with the Procise ADL assay, it binds to the donor labeled TNFα protein allowing the anti-ADL/TNFα Fab' antibody bound to an acceptor to bind.

Once the labeled TNFα protein and anti-ADL/TNFα Fab' antibody are bound together within a complex, their close proximity allows for fluorescence resonance energy transfer (FRET) to occur. The acceptor fluorophore emission created from FRET is measured along with the donor signal. The ratio of the two emissions is used by the ProciseDx Analyzer to determine the concentration of ADL within the sample. The acceptor to donor ratio is proportional to the amount of ADL in the sample.

V Standards/Guidance Documents Referenced:

CLSI EP05-A3, 3rd Edition, 2015, Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline

CLSI EP06 2nd Edition, 2021, Evaluation of the Linearity of Quantitative Measurement Procedures

CLSI EP07 3rd Edition, 2018, Interference Testing in Clinical Chemistry

CLSI EP09c 3rd Edition, 2020, Measurement Procedure Comparison and Bias Estimation Using Patient Samples

CLSI EP17-A2, 2013, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline

CLSI EP25-A, 2013, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.

CLSI EP37 1st Edition, 2018, Supplemental Tables for Interference Testing in Clinical Chemistry

CLSI EP32-R, 2014, Metrological Traceability and Its Implementation; A Report

VI Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:

   Precision studies were conducted following the recommendations in CLSI EP05-A3 guideline.

   Precision studies were performed using five pools of native ADL serum samples with targeted ADL concentrations at approximately 2.8, 6, 10, 14, and 45 µg/mL. Three lots of Procise ADL assay reagents were paired with three lots of buffer bulbs using three different

instruments. The paired assay lot and instruments were changed from the first daily run compared to the second. Samples were tested in replicates of two, two times per day, for twenty days. The precision results characterize the precision of the Procise ADL assay across the measurement range and are summarized below for all lots.

Procise ADL Assay Precision (20-Day) for All Reagent Lots and Analyzers

Sample	N	Mean (µg/mL)	Between Lot		Between Analyzer		Between Day		Between Run		Within Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	240	2.47	0.12	4.8%	0.12	4.9%	0.05	2.2%	0.01	0.6%	0.19	7.8%	0.26	10.6%
2	240	5.79	0.26	4.6%	0.11	1.9%	0.07	1.2%	0.02	0.3%	0.26	4.5%	0.40	6.8%
3	240	10.22	0.26	2.6%	0.21	2.0%	0.10	0.9%	0.04	0.4%	0.51	5.0%	0.62	6.1%
4	240	12.71	0.29	2.3%	0.17	1.3%	0.14	1.1%	0.06	0.5%	0.85	6.7%	0.93	7.3%
5	240	45.79	0.49	1.1%	0.25	0.5%	0.18	0.4%	0.17	0.4%	2.31	5.0%	2.39	5.2%

A reproducibility study was performed at three external sites. Reproducibility studies were performed using five serum samples consisting of three pools of native serum samples with ADL concentrations approximately 5, 10, and 40 µg/mL and two serum quality control samples with ADL concentrations of 3.2 and 22.8 µg/mL. The same Procise ADL assay lot was used at all three sites. At each site, samples were tested in replicates of three, two times per day, for five days by two operators using two instruments. The reproducibility results characterize the precision of the Procise IFX assay across the measurement range and are summarized below for all lots.

Procise ADL Assay Reproducibility for All Sites

Sample	Mean (µg/mL)	Within Run		Between Run		Between Day		Between Instrument		Between Operator		Between Site		Total	
		SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
QC Low	3.20	0.20	6.2	0.04	1.3	0.08	0.3	0.03	1.0	0.06	1.9	0.07	2.1	0.22	7.0
QC High	22.77	1.34	5.9	0.49	2.1	0.35	1.5	0.25	1.1	0.52	2.3	0.41	1.8	1.63	7.2
1	5.18	0.24	4.6	0.06	1.2	0.06	1.2	0.09	1.6	0.13	2.5	0.12	2.3	0.32	6.2
2	9.77	0.53	5.4	0.10	1.0	10.11	1.1	0.11	1.1	0.16	1.6	0.15	1.5	0.60	6.1
3	44.32	3.27	7.3	0.80	1.8	0.76	1.7	0.58	1.3	1.05	2.4	1.50	3.4	3.95	8.9

2. Linearity:

Linearity studies were conducted following the recommendations in CLSI EP06 2nd edition guideline.

A linearity study was conducted to evaluate linearity across the measuring range of the Procise ADL assay. Serum samples with 13 different ADL levels were evaluated: 0.5, 0.8, 1.4, 2.1, 3.1, 4.6, 6.9, 10.2, 15.9, 23.0, 34.3, 51.6 and 74.9 µg/mL. A native serum sample with ADL concentrations of 18.1 µg/mL was spiked with ADL Intermediate Dilution (PN4707) µg/mL) to obtain a concentration of 84.0 µg/mL. This was mixed with a native serum pool with no ADL to achieve the 13 different levels of ADL tested. The linear regression results are shown below. The percent deviation from linearity was within ±5% across the reportable range of the assay.

Claimed Measuring Range	**Sample Range Tested**	**Slope**	**Intercept**	**R^2**
1.0-50 µg/mL	0.5-74.9 µg/mL	0.98	0.28	0.9995

These results support the claimed measuring range of 1.0 to 50 µg/mL for ADL.

A second linearity study was conducted with native samples. A pool of negative native serum was mixed in known ratios with a single ADL native serum sample with an ADL concentration of 28.1 µg/mL measured by the Procise ADL assay to create eleven serum levels known relative to one another. The percent deviation from linearity was within ±5% across the range of the assay tested.

3. Analytical Specificity/Interference:

Interference studies were conducted following the recommendations in CLSI EP37 guideline.

Each potentially interfering substance was prepared at twice the CLSI recommended level in pooled ADL negative serum which was then combined at a 1:1 ratio with native ADL serum sample pools to obtain ADL serum concentrations at approximately 5 and 25 µg/mL plus the interferent. The control samples without interferent were made by combining the native ADL serum at each level with ADL negative serum at a 1:1 ratio. None of the substances in the tables below showed significant interference, defined as bias ≤10% for each potential interferent and concentration level tested when compared to the nominal condition.

List of interferents at their concentration up to which no interference was observed.

Compound	**Tested concentration**
5-aminosalicylate	2.04 mg/dL
6-mercaptopurine	0.148 mg/dL
Acetaminophen	15.6 mg/dL
Acetylsalicylic Acid	3 mg/dL
Antidrug antibodies to ADL	200 ng/mL
Ascorbic Acid	5.25 mg/dL
Azathioprine	0.258 mg/dL
Bilirubin Conjugated	20 mg/dL
Bilirubin Unconjugated	40 mg/dL
Budesonide	0.0146 µmol/L
Ciprofloxacin	1.2 mg/dL

Compound	Tested concentration
Hemolysate	800 mg/dL
Human Anti-Mouse Antibody	200x
Infliximab	20 µg/mL
Methotrexate	2000 µmol/L
Metronidazole	12.3 mg/dL
Prednisone	0.276 µmol/L
Rheumatoid Factors	1285 IU/mL
Sulfasalazine	7.5 mg/dL
Total Protein	15 g/dL
Triglycerides	1500 mg/dL
Vitamin D	300 ng/mL

The sponsor included the following limitation in the labeling:
Note: Due to possibility of introducing error, highly hemolyzed (>800 mg/dL hemolysate) or highly icteric (>20 mg/dL conjugated bilirubin) samples should not be tested in the Procise ADL assay.

High-Dose Hook Effect
To evaluate the potential for a high dose hook effect in the Procise ADL assay, serum samples were tested at ADL concentrations of approximately 25, 50, 100, 200 and 300 µg/mL. The samples were tested in replicates of five using three assay lots and three buffer bulb lots. For results above the Procise ADL assay upper limit of quantification (50 µg/mL), the ProciseDx Analyzer displayed >50 µg/mL as a result. Device results are unimpacted by a hook effect at ADL concentrations of up to 300 µg/mL.

4. Assay Reportable Range:

The assay reportable range is from 1.0 to 50.0 µg/mL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability
The Procise ADL assay calibration standards are traceable to the ADL WHO International Standard: 1st International Standard for Adalimumab (NIBSC code:17/236).

Procise ADL Assay Recovery Study
A study was performed to assess the functional accuracy of the Procise ADL assay calibration and control methodology. 50 µg of the WHO IS Standard for ADL was reconstituted using 1.0 mL of pooled native negative serum to achieve a known starting concentration of 50 µg/mL. Native ADL negative serum was used to dilute the starting sample to create a total of 11 samples, each one-third less than the previous. These 11 dilutions were tested in triplicates using one lot of the Procise ADL assay components in singlicate. The results are summarized below individually for three replicates.

Procise ADL Result vs. WHO IS Standard for ADL Linear Regression Results

Analyte	Replicate	Slope	Y-Intercept	R^2
ADL	1	1.03	0.11	1.00
	2	0.99	0.29	1.00
	3	1.03	0.05	1.00

Procise ADL Result Summary When Testing the WHO IS Standard for ADL

WHO IS [ADL] (µg/mL)	Replicate	Procise [ADL] (µg/mL)	% Bias	%CV
50.0	1	51.3	3%	3%
	2	48.6	-3%	
	3	50.7	1%	
33.3	1	35.0	5%	1%
	2	34.5	4%	
	3	35.4	6%	
22.2	1	22.6	2%	2%
	2	23.4	5%	
	3	22.6	2%	
14.8	1	15.5	5%	2%
	2	14.9	1%	
	3	14.8	0%	
9.9	1	9.4	-4%	4%
	2	10.0	1%	
	3	10.3	4%	
6.6	1	6.7	1%	3%
	2	6.9	4%	
	3	6.5	-2%	
4.4	1	5.0	13%	6%
	2	4.4	1%	
	3	4.5	2%	
2.9	1	3.0	4%	2%
	2	3.1	7%	
	3	3.0	4%	
2.0	1	2.2	14%	8%
	2	2.0	4%	
	3	1.9	-3%	
1.3	1	1.6	21%	11%
	2	1.3	3%	
	3	1.3	0%	

Sample Stability

Room Temperature and Refrigerated
To test the stability of serum specimens at room temperature or at 4°C, the sponsor performed a stability study using freshly drawn serum from three patients (targeting low, mid, and high range ADL concentrations) receiving ADL therapy. Refrigerated (~4°C) and room temperature (~22°C) specimens were tested in duplicate at Baseline, defined as 2-4 hours after draw (Day 0), Day 1, Day 3, Day 5, and Day 7 using three different lots of Procise ADL reagents. The results support the labeling claim of three days of stability at room temperature or refrigerated (4°C).

Frozen Serum Stability
The sponsor performed a frozen serum stability study to demonstrate that serum samples stored at -80°C that contain ADL are stable when measured with the Procise ADL assay. The sponsor performed the stability study using freshly drawn serum from 33 patients, tested by using the Procise ADL assay within a day of draw. Samples were stored frozen at -80°C then thawed and retested in duplicate using one lot of Procise ADL assay reagents. The results show that serum samples with ADL stored at -80°C are stable up to 142 weeks.

Freeze-Thaw Serum Stability
The sponsor performed a freeze-thaw study to test the stability of frozen clinical serum specimens stored at -80°C that contain ADL when the samples undergo multiple freeze-thaw cycles. The sponsor tested five frozen serum samples with ADL concentrations of ~3, 5, 7, 20, and 40 µg/mL, previously measured using the Procise ADL assay when freshly collected. Each sample was tested after 1, 2, 3, and 5 freeze-thaw cycles and the ADL results were compared back to the original pre-frozen value. The results show that ADL is stable in serum samples frozen at -80°C that have undergone up to five freeze-thaw cycles.

6. Detection Limit:

Detection limits were assessed following the recommendations in CLSI EP17-A2 guideline.

The limit of blank (LoB) was determined using four native serum specimens containing no ADL. Each of the four serum samples were tested in replicates of five over three days using two Procise ADL assay lots for a total of 60 measurements per reagent lot. The 95th percentile from each reagent lot was calculated, multiplied by the standard deviation of the blank and the result was added to the mean of the blank to calculate the LoB for each lot. The sponsor determined the LoB to be 0.08 µg/mL which was the highest LoB calculation between the two Procise ADL assay lots.

The limit of detection (LoD) was determined using four different ADL serum samples with the concentrations: 0.1, 0.2, 0.4 and 0.5 µg/mL. Each of the four serum samples were tested in replicates of five across three days using two Procise ADL assay reagent lots for a total of 60 measurements per lot. Two operators performed the testing. A one-sided 95% confidence t-distribution table (with a sample size of 60) was used to calculate a multiplier. To calculate the LoD, this multiplier was multiplied by the pooled standard deviations for 60 data points for each assay lot then the result was added to the LoB. The sponsor determined the LoD to be 0.25 µg/mL using the assay lot with the highest LoD determination.

The limit of quantitation (LoQ) was determined using four to five (depending on the Procise ADL assay reagent lot) samples above the LoD with ADL concentrations at: 0.7, 0.9, 1.1 and 1.4 µg/mL (Lot 1) and 0.4, 0.5, 0.7, 0.9 and 1.1 µg/mL (Lot 2). Each of the four serum samples were tested in replicates of five across three days using two Procise ADL assay reagent lots for a total of 60-75 measurements per lot. Two operators performed the testing. The LoQ was determined to be 0.96 µg/mL at which they observed <35% total error.

7. Assay Cut-Off:

   See Assay Reportable Range section above.

8. Accuracy (Instrument):

   See Traceability and Method comparison sections.

9. Carry-Over:

   Not applicable, the Procise ADL assay cartridge is single use.

B Comparison Studies:

1. Method Comparison:

   A method comparison study was conducted comparing the Procise ADL assay to two validated comparator methods. A total of 62 deidentified serum samples were tested with the Procise ADL assay and the results were compared to results from Comparators 1 and 2. Data was analyzed using weighed Deming regression and Pearson correlation. The results for a representative comparator method are summarized below.

   Procise ADL vs. Comparator

N	Slope	Intercept (µg/mL)	Correlation Coefficient (r)	Sample range tested (µg/mL)
61	0.91	1.08	0.994	2.15-42.7

2. Matrix Comparison:

   Not applicable. Not applicable. Serum is the only matrix claimed for the Procise ADL assay.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Clinical therapeutic drug monitoring (TDM) for adalimumab is based on the understanding that there is a relationship between drug exposure and clinical outcomes when treating patients with IBD with therapeutic biologics. Inter-individual variability exists in the rate of clearance of therapeutic biologics, including for adalimumab; therefore, having information that helps clinicians understand whether a patient is clearing the drug faster than expected provides information that aids clinicians in the management of their patients. The Procise ADL assay is intended to quantitatively detect the presence (or absence) of adalimumab in patients with IBD receiving adalimumab therapy. Published literature and professional society practice guidelines on the use of TDM in patients with IBD receiving adalimumab support that the device output (i.e., detecting the presence of adalimumab) provides information that is clinically meaningful to aid healthcare providers in the management of patients with IBD.

In patients with IBD who have active disease, detecting the presence or absence of circulating drug is useful to aid clinicians in clinical decision-making. As noted in the U.S. clinical practice guideline "American Gastroenterological Association Institute Guideline on Therapeutic Drug Monitoring in Inflammatory Bowel Disease" (2017), failure of treatment with adalimumab is generally due to one of two possibilities: 1) mechanistic failure or 2) pharmacokinetic failure. Pharmacokinetic failure occurs when therapeutic levels of drug are not achieved/maintained. Pharmacokinetic failure can occur via either immune or non-immune mediated pathways. In immune-mediated PK failure, anti-drug antibody formation results in increased drug clearance and reduced or undetectable levels of the drug.

Regardless of the cause of the undetectable drug level, understanding whether a patient has circulating drug present is informative, as therapeutic proteins can exert beneficial clinical effects only when circulating at concentrations that allow interaction between the antibody and the target receptor, leading to downstream pharmacodynamic effects.

In summary, there is available evidence to support that the "detectable" or "not detectable" quantitative output from the Procise ADL assay will provide meaningful information to clinicians to aid in determining whether a lack of therapeutic response may be due, at least in part, to lack of circulating drug. Including the measured quantitative level can help the physician put the result into context.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Performance Characteristics Data:

Procise ADL Assay Biosimilars

To demonstrate that the Procise ADL assay can accurately detect an Adalimumab biosimilar drug (Amjevita), a pool of ADL negative human serum was used to create seven different levels each of Adalimumab and Amjevita: 2.5, 5, 10, 20, 30, 40, and 50 µg/mL. Each biosimilar concentration, as well as the ADL control, was tested in replicates of six. The results are summarized below.

Procise ADL Serum Biosimilar Drug Results

ADL Biosimilar	Expected [ADL] µg/mL	Observed [ADL biosimilar] µg/mL (n=6)	% Bias
Amjevita®	53.3	58.7	10%
	44.4	45.4	2%
	33.1	32.8	-1%
	22.0	23.4	6%
	10.8	11.4	6%
	5.5	5.5	-1%
	2.8	2.9	1%

The data show that the Procise ADL assay demonstrates quantitative equivalence in measuring Amjevita®. The sponsor included the following statements in the labeling:

Procise ADL is validated to monitor drug levels of biological drugs which contains the active substance Adalimumab, that is the original drug Humira® and biosimilar drug Amjevita®. Additional biosimilar drugs have not been validated.
Compatibility with the Procise ADL Assay was confirmed for biosimilar drug Amjevita® with at seven (7) concentrations ranging from 3 to 50 µg/mL. Serum has a linear regression coefficient of determination (R^2) of 1.0 for the biosimilar.

VII Proposed Labeling:

The labeling supports the decision to grant the De Novo request for this device.

VIII Identified Risks and Mitigations:

Risks to Health	Mitigation Measures
Incorrect test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.
Incorrect interpretation of test results	Certain design verification and validation activities and documentation, including certain studies. Certain labeling information, including certain limiting statements.

IX Benefit/Risk Assessment:

A Summary of the Assessment of Benefit:

There are currently no devices with FDA marketing authorization for determining adalimumab blood concentrations. The accuracy of the device is adequate to support clinical benefit when the device is used solely as noted in the indications for use.

In general, there is a risk of anti-drug antibody (ADA) development during treatment with therapeutic proteins, including adalimumab. Although the approved dosing regimen is intended to maintain an acceptable level of circulating drug, development of anti-drug antibodies, or other intrinsic factors affecting clearance, may lead to a reduced drug level or absence of detectable drug level during treatment. The clinical benefit of the Procise ADL assay is that it can quantitatively detect the presence (or absence) of adalimumab. This can help determine whether a lack of therapeutic response is due, at least in part, to lack of detectable drug. Providing the "detectable" or "not detectable" quantitative output will provide useful information to physicians and including the measured level can help them put this result into context.

B Summary of the Assessment of Risk:

The risks with use of the device are associated with misclassification due to incorrect test results (i.e., falsely high and falsely low test results) and incorrect interpretation of results such as interpreting a particular target trough concentration as optimal when there is not sufficient data to support this claim.

C Patient Perspectives:

This submission did not include specific information on patient perspectives for this device.

D Summary of the Assessment of Benefit-Risk:

The clinical benefit of the Procise ADL assay is having a determination of the presence or absence of adalimumab in IBD patients, with the quantitative level provided for context. In

patients with active disease, understanding whether they have detectable trough levels is informative for clinicians to aid in clinical management. Development of anti-drug antibodies can occur at any time during treatment and can increase drug clearance and lead to an undetectable trough level, which may impact the efficacy of the drug.

When the device is used as intended, the risks are mitigated by the Procise ADL assay indications for use, which do not propose therapeutic or reference ranges or refer to any action a clinician should take, such as dose adjustment, and the special controls. The output of the Procise ADL assay is intended to be used as one piece of information, taking into consideration many other factors such as the patient's clinical status and other laboratory test values. The device provides information regarding whether a patient has circulating drug at the time of testing. It is not intended to be used to make treatment decisions/change in medical management in isolation The indications for use, along with special controls which require appropriate device verification and validation testing to support all clinical and analytical claims, are sufficient to mitigate the risks associated with misclassification due to incorrect test results (i.e., falsely high and falsely low test results) and incorrect interpretation of results.

Device design verification and validation activities, including studies to support all analytical claims, clinical claims, and testing environments to ensure acceptable clinical and analytical performance, as well as certain labeling information will help ensure that the device functions as intended and mitigate the risk of incorrect test results (i.e., falsely low or falsely high test results) or the incorrect interpretation of the test results.

While general controls are insufficient to mitigate the risks of the device, the probable benefits outweigh the probable risks for the Procise ADL assay, considering the indications for use and the mitigation of the risks provided by the special controls. Overall, the probable benefits outweigh the probable risks of incorrect test results or incorrect interpretation of test results for the proposed indications for use, in light of the special controls and general controls.

X Conclusion:

The De Novo request is granted and the device is classified under the following and subject to the special controls identified in the letter granting the De Novo request:

Product Code(s): QYD
Device Type: Anti-tumor necrosis factor alpha monoclonal antibody test system for inflammatory bowel disease
Class: II (Special Controls)
Regulation: 21 CFR 862.3115