Imperative Care Inc.
Jake Wolenberg
Regulatory Affairs Manager
1359 Dell Avenue
Campbell, California 95008

September 2, 2020

Re: K202182
Trade/Device Name: ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 31, 2020
Received: August 4, 2020

Dear Jake Wolenberg:

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); 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,

Naira Muradyan, Ph.D.
Assistant Director (Acting)
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202182

Device Name
ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing

Indications for Use *(Describe)*
The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The ZOOM Aspiration Tubing is intended to connect the ZOOM Reperfusion Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.

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.

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Special 510(k) Summary
ZOOM™ Reperfusion Catheters and Aspiration Tubing

A. Submitter Information

Submitter's Name:	Imperative Care Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Jake Wolenberg
Telephone:	248-496-0198
Email:	JWolenberg@imperativecare.com
Date of Preparation:	July 31, 2020

B. Subject Device

Proprietary Name:	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Catheter, Percutaneous
Product Code:	NRY per 21 C.F.R. 870.1250

C. Predicate Device

Proprietary Name:	MantaRay (071, 055, 045, 035) Reperfusion Catheters; Imperative Care Aspiration Tubing Set
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Catheter, Percutaneous
Product Code:	NRY per 21 C.F.R. 870.1250
Manufacturer:	Imperative Care Inc.
510(k) #:	K183043

D. Device Description:

The ZOOM Reperfusion Catheter is a single lumen, braid and coil reinforced, variable stiffness catheter that facilitates removal of thrombus/clot from the neurovasculature when connected to a vacuum source, such as the ZOOM Aspiration Pump, using the ZOOM Aspiration Tubing.

The ZOOM Reperfusion Catheter is offered in various working lengths and nominal inner diameters (ID) and outer diameters (OD) as shown in **Table 1** below.

Table 1: ZOOM Reperfusion Catheter Sizes

Product Name (Used Throughout 510k)	Model Number	Distal Diameter		Proximal Diameter		Nominal Usable Catheter Length	Hydrophilic Coating Length
		Inner	Outer	Inner	Outer		
ZOOM 71	ICRC071137	0.071”	0.083”	0.071”	0.083”	137 cm	35cm
ZOOM 55	ICRC055137	0.055”	0.069”	0.067”	0.080”	137 cm	35cm
ZOOM 45	ICRC045144	0.045”	0.060”	0.064”	0.080”	144 cm	65cm
ZOOM 35	ICRC035158	0.035”	0.051”	0.047”	0.061”	158 cm	90cm

The ZOOM Reperfusion Catheter is comprised of a hollow cylindrical tube which is bonded to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers.

The distal section of the ZOOM Reperfusion Catheter has a hydrophilic coating to enhance tracking through the vasculature. The beveled distal tip allows for atraumatic tracking past vessel branches during insertion. A radiopaque marker provides the user with visual confirmation of the distal tip location under fluoroscopy.

The ZOOM Reperfusion Catheter is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is designed to be attached to the proximal luer of the catheter and helps the user maintain hemostasis.

The ZOOM Aspiration Tubing is offered in one model with the features indicated in **Table 2**.

Table 2: ZOOM Aspiration Tubing Models

Product Name (Used Throughout 510k)	Model Number	Tubing ID	Tubing Length
ZOOM Aspiration Tubing	TAT102B	0.110” Minimum	104”

The ZOOM Reperfusion Tubing is comprised of a hollow cylindrical tube which is bonded to a standard luer fitting that connects to the ZOOM Reperfusion Catheter and a slip fit connector that connects to the canister on the aspiration pump. The ZOOM Aspiration tubing is made of common medical grade polymers.

In addition to the accessories discussed above, the adjunctive devices and supplies listed below are intended to be used with the ZOOM Reperfusion Catheter and Aspiration Tubing.

- Guidewires
- Support/Diagnostic Catheters
- Introducer Sheaths
- Aspiration Pump*
  - Capable of achieving pressure between -20inHg to max vacuum
  - Airflow rating of 0 – 23 LPM
  - IEC 60601-1 Compliant

*Imperative Care offers the ZOOM Aspiration Pump which meets the indicated criteria.

E. Indications for Use:

The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The ZOOM Aspiration Tubing is intended to connect the ZOOM Reperfusion Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.

F. Predicate Comparison:

The predicate device for the ZOOM Reperfusion Catheter and Aspiration Tubing in this Special 510(k) is the prior generation of ZOOM Reperfusion Catheter and Aspiration Tubing cleared under 510(k) K183043 with device name MantaRay (071, 055, 045, 035) Reperfusion Catheters; Imperative Care Aspiration Tubing Set. For ease of review the subject device is referred to as "Gen 2" and the predicate device cleared under 510(k) K183043 is referred to as "Gen 1" throughout the rest of this 510(k) Summary. **Table 3** presented below provides a comparison of the similarities and differences between the Gen 1 and Gen 2 ZOOM Reperfusion Catheter and Aspiration Tubing.

The comparison between the subject and predicate devices demonstrates that Gen 2 ZOOM Reperfusion Catheter and Aspiration Tubing are substantially equivalent to the predicate Gen 1 versions of these devices and that there are no new safety or effectiveness concerns. This conclusion is based on all devices sharing the same intended use, basic technology characteristics, and performance characteristics, as demonstrated through bench and lab testing.

Table 3: Subject and Predicate Device Comparison

Device Attribute	Gen 1 ZOOM Reperfusion Catheter (Predicate Device)	Gen 2 ZOOM Reperfusion Catheter (Subject Device)
FDA Product Classification	Class II, NRY, 21 CFR 870.1250	Same
Intended Use	Revascularization of patients with acute ischemic stroke.	Same
Indications for Use	See Section E.	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same
Nominal Distal Inner Diameter	0.035" – 0.071"	Same
Max Distal Outer Diameter	0.053" – 0.085"	Same
Nominal Proximal Inner Diameter	0.047" – 0.071"	Same
Max Proximal Outer Diameter	0.062" – 0.085"	Increased by 0.001" for all sizes
Effective Length	137 - 158cm	Same
Tip Design	Beveled edge, soft, flexible, and atraumatic	Same
Tip Length	0.5 – 1.5cm	0.5 – 0.8cm

Device Attribute	Gen 1 ZOOM Reperfusion Catheter (Predicate Device)	Gen 2 ZOOM Reperfusion Catheter (Subject Device)
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same
Packaging Configuration	The catheter is placed in a protective polyethylene tube and then mounted, along with the accessories, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and IFU are placed in a carton box.	Same
Aspiration Pump	ZOOM Aspiration Pump	Same
Device Attribute	**Gen 1 ZOOM Aspiration Tubing (Predicate Device)**	**Gen 2 ZOOM Aspiration Tubing (Subject Device)**
Indications for Use	See Section E	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same
Tubing ID	0.110” Minimum	Same
Tubing Length	112”	104”
Flow Control Mechanism	Flow Control Switch	Flow Control Clamp

G. Performance Data Supporting Substantial Equivalence:

Bench testing was conducted to evaluate the similarities and differences between the subject and predicate devices. The largest and smallest diameter catheters were tested for both the subject and predicate devices.

The test results were reviewed and found to demonstrate that the differences between the subject and predicate devices do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject Gen 2 ZOOM Reperfusion Catheter and Aspiration Tubing.

A summary of the tests and performance specifications that were evaluated is presented in **Tables 4 and 5**. These tests were performed per company approved protocols and test methods based primarily on catheter performance standard ISO 10555-1.

Table 4: Tests and Performance Specifications for ZOOM Reperfusion Catheter

Test Attribute	Specification
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurological model without incurring any damage to the catheter.
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.
Compatibility with other devices (external)	The catheters shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.
Guidewire compatibility	The catheters shall be able to be delivered over the guidewire size indicated in the product labeling.
Interventional device compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling.
Luer compatibility	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.
Accessory compatibility	Devices shall be compatible with the accessory RHV.
Visual	Free of kinks, breaks, separation or particulate (greater than 0.25mm^2). No exposed metal.

Test Attribute	Specification
Dimensional	All defined catheter dimensions are within the specified tolerances.
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.
Flowrate – positive (forward) pressure	The catheter lumen shall allow for a minimum flowrate comparable to competitive products.
Flowrate – vacuum pressure	The flowrate under a vacuum shall be similar to or greater than competitive devices.
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.
Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.
Catheter Torque Strength	No separation of any portion of the catheter when rotated at least two (2) full rotations (720 degrees).
Lumen Integrity	The catheter lumen shall not collapse under vacuum after multiple passes.
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) at anatomically relevant bend radii.
Flexibility	The flexibility of the catheter tip shall be comparable to competitive products and allow for easily tracking the device to the desired target anatomy.
Coating - Particulate	The amount of particulate matter that comes off the hydrophilic-coated shaft during simulated use testing shall be determined and compared to competitive products and techniques.

Table 5: Tests and Performance Specifications for ZOOM Aspiration Tubing

Test Attribute	Specification
Vacuum Force at Catheter Tip	The vacuum force delivered by the aspiration tubing to the tip of the catheter should be comparable to the vacuum force delivered by the predicate aspiration tubing.
Connector Compatibility	The aspiration tubing connectors shall securely connect to the pump canister lid and standard luer fittings.
Lumen Collapse Test	The tubing lumen shall not collapse under vacuum.
Flow Control Functionality	The flow control mechanism shall allow users to start and stop flow multiple times when the connected pump is running at maximum vacuum.
Freedom From Leakage	The vacuum pressure delivered at the tip of the aspiration tubing shall be consistent with the pressure generated by the pump.
Tensile Strength	The bonds between the tubing and connectors shall be sufficiently strong to ensure the tubing remains intact during use.

In addition to the above tests which support that the Gen 2 ZOOM Reperfusion Catheter and Aspiration Tubing perform as intended when used with the ZOOM Aspiration Pump, general performance testing was also completed for the accessory ZOOM Aspiration Pump as documented in 510(k) K190105.

H. Biocompatibility Testing:

While there are no new patient contacting materials for the Gen 2 ZOOM Reperfusion Catheters, a subset of supporting biocompatibility testing was completed per Imperative Care's risk management and change control procedures to confirm that the Gen 2 design and manufacturing updates did not result in any significant changes to the biocompatibility of the ZOOM Reperfusion Catheters.

The changes made to the Gen 2 ZOOM Aspiration Tubing were also reviewed and it was determined that no new biocompatibility testing was necessary to implement these changes as the aspiration tubing is non-patient contacting and there were no manufacturing process updates associated with the changes that were made.

The test results for the Gen 2 ZOOM Reperfusion Catheter were compared against the test results for the Gen 1 ZOOM Reperfusion Catheter, as summarized below in **Table 6** and no significant differences were noted that would negatively impact the biocompatibility of the Gen 2 ZOOM Reperfusion Catheters.

Table 6: Biocompatibility Test Summary

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Cytotoxicity: ISO MEM* Elution	ISO 10993-5	Test device extracted in MEM with 5% serum at 37 ± 1°C for 24 ± 2 hours	Sample extracts must yield cell lysis grade 2 or lower.	**Pass, Non-cytotoxic**
Cytotoxicity: ISO MTT* Assay	ISO 10993-5	Test device extracted in MTT* Assay Media at 37 ± 1°C for 24 ± 2 hours	The percentage of cells exhibiting lysis should be similar for all test devices.	**Pass, No Significant Differences**
Hemocompatibility: Hemolysis (Extract Method)	ASTM F 756 ISO 10993-4	Test device extracted in PBS at 50 ± 2°C for 72 ± 2 hours. Extract exposed to blood cell suspension. % hemolysis is measured.	Sample extracts must be nonhemolytic (≤ 2% hemolytic index).	**Pass, Non-hemolytic**

*MEM=Minimal Essential Media,
MTT Assay = (3-(4,5-Dimethylthiazol-2-yl)-2,5-Diphenyltetrazolium Bromide)
NS = Normal Saline
PBS=Phosphate Buffered Saline

I. Sterilization:

The ZOOM Reperfusion Catheter and Aspiration Tubing are both sterilized using validated EO processes with a sterility assurance level of $1x10^{-6}$. The sterilization processes were validated per the overkill method described recognized consensus standard ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices." A summary of the completed testing is presented below in **Tables 7 and 8**.

Table 7: Sterilization Validation Summary – ZOOM Reperfusion Catheter

Requirement/Acceptance Criteria	Results	Summary
Positive BI controls must be positive in fractional, half and full cycles.	**PASS**	All positive controls in each cycle read positive.
Fractional cycle requirements: 1) IPCDs and EPCDs must be more difficult to sterilize than the natural product. 2) Product Sterility testing must show no growth in all samples. 3) Bacteriostasis/Fungistasis testing must show that the product is not inhibitory for growth.	**PASS**	1) IPCDs and EPCDs showed more growth than natural product. 2) The devices did not show any growth when tested per the methods in ISO 11737-2. 3) Bacteriostasis/Fungistasis Testing showed product is not inhibitory to growth when tested per the methods in ISO 11737-2.

Requirement/Acceptance Criteria	Results	Summary
Half cycle requirements: 1) IPCDs and EPCDs should show no growth for all samples.	**PASS**	1) IPCDs and EPCDs showed no growth.
Full cycle requirements: 1) IPCDs and EPCDs must show no growth for all samples. 2) The results for Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) shall meet the requirements of ISO 10993-7.	**PASS**	1) IPCDs and EPCDs showed no growth. 2) Samples passed EO residual testing.

Table 8: Sterilization Validation Summary – ZOOM Aspiration Tubing

Requirement/Acceptance Criteria	Results	Summary
Positive BI controls must be positive in fractional, half and full cycles.	**PASS**	All positive controls in each cycle read positive.
Fractional cycle requirements: 1) IPCDs and EPCDs must be more difficult to sterilize than the natural product. 2) Product Sterility testing must show no growth in all samples. 3) Bacteriostasis/Fungistasis testing must show that the product is not inhibitory for growth.	**PASS**	1) IPCDs and EPCDs showed more growth than natural product. 2) The devices did not show any growth when tested per the methods in ISO 11737-2. 3) Bacteriostasis/Fungistasis Testing showed product is not inhibitory to growth when tested per the methods in ISO 11737-2.
Half cycle requirements: 1) IPCDs and EPCDs should show no growth for all samples.	**PASS**	1) IPCDs and EPCDs showed no growth.
Full cycle requirements: 1) IPCDs and EPCDs must show no growth for all samples. 2) The results for Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) shall meet the requirements of ISO 10993-7.	**PASS**	1) IPCDs and EPCDs showed no growth. 2) Samples passed EO residual testing.

J. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify device, accessory, and packaging performance. A minimum shelf life was established based on this testing and is indicated by the expiration date provided on the product labeling.

Device and accessory performance was verified by repeating the functional tests previously presented in Section G of this 510(k) summary.

Packaging and sterile barrier integrity through transportation has been verified for the packaging configurations used for the ZOOM Reperfusion Catheter and ZOOM Aspiration Tubing. Aging testing has also been performed that supports the sterile barrier integrity following aging. A summary of the completed packaging tests is presented below in **Tables 9 and 10**.

Table 9: Packaging Validation Summary – ZOOM Reperfusion Catheter

Test	Test Method	T0 Results (Pass/Fail)	Shelf Life Results (Pass/Fail)
Packaging Visual Inspection	ASTM F1886 Imperative Care Internal	Pass	Pass
Pouch Integrity Test – Gross Leak Detection	ASTM F2096	Pass	Pass
Pouch Seal Strength – Peel Strength	ASTM F88	Pass	Pass
Label Integrity	Imperative Care Internal	Pass	Pass

Table 10: Packaging Validation Summary – ZOOM Aspiration Tubing

Test	Test Method	T0 Results (Pass/Fail)	Shelf Life Results (Pass/Fail)
Packaging Visual Inspection	ASTM F1886 TWBM Internal	Pass	Pass
Pouch Integrity Test – Gross Leak Detection	ASTM F2096	Pass	Pass
Pouch Seal Strength – Peel Strength	ASTM F88	Pass	Pass
Label Integrity	TWBM Internal	Pass	Pass

K. Conclusions:

Where differences were identified between the subject Gen 2 ZOOM Reperfusion Catheter and Aspiration Tubing and the predicate Gen 1 ZOOM Reperfusion Catheter and Aspiration Tubing, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns regarding the use of the device. As appropriate, bench and lab testing were conducted to support this assessment.

Based on the results of the completed risk assessments and associated testing, it is concluded that the subject Gen 2 ZOOM Reperfusion Catheter and Aspiration Catheter is substantially equivalent to the predicate Gen 1 ZOOM Reperfusion Catheter and Aspiration Tubing and that there are no new safety or effectiveness concerns associated with the identified differences. This conclusion is supported by the subject and predicate devices sharing the same intended use, basic technology characteristics, and equivalent performance characteristics, as confirmed through well-designed bench and lab testing.