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## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (HHS) (collectively, the “United States”); Semler Scientific, Inc. (“Semler”); and Robert Kane and Franklin W. West (collectively, “Relators”), hereafter collectively referred to as “the Parties,” through their authorized representatives.

### RECITALS

A. Semler is a medical device manufacturer and distributor headquartered in Campbell, California.

B. From 2010 through 2024, Semler manufactured, marketed, and distributed two plethysmography devices—Flohec and QuantaFlo (the “Devices”)— directly, and at times through distributors, to customers throughout the United States.

C. On December 7, 2016, Relators filed a *qui tam* action in the United States District Court for the Middle District of Florida captioned *United States ex rel. Kane v. Semler Scientific, Inc.*, Case No. 3:16-CV-1516, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (“the Civil Action”).

D. The United States contends that Semler caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (“Medicare”).

E. The United States contends that it has certain civil claims against Semler arising from the following conduct, which is referred to below as the “Covered Conduct”:

The United States contends that from 2010 through 2024, Semler violated the False Claims Act, 31 U.S.C. §§ 3729-3733, by knowingly causing, and conspiring to cause, the

submission of false claims to Medicare Part B for tests performed using the FloChec and QuantaFlo devices. FloChec and QuantaFlo use a single clip-on light sensor that is attached to the fingers and toes to generate a photoplethysmographic waveform.

### **Peripheral Arterial Disease and Relevant Regulations**

Peripheral arterial disease (PAD) in the legs or lower extremities is the narrowing or blockage of the vessels that carry blood between the heart and legs.

To be reimbursable, plethysmographic testing for PAD must satisfy Current Procedural Terminology (“CPT”) codes 93922, 92923, or 93924. All three codes require that a provider perform an ankle brachial index (“ABI”) *plus* certain enumerated additional testing. To conduct an ABI, a healthcare professional measures the patient’s blood pressure in both arms and both ankles using an inflatable cuff and a hand-held ultrasound device that is pressed on the skin. By comparing the pressure in the arms against the pressure in the ankles, the healthcare professional can estimate the severity of PAD in a patient’s limbs and recommend a course of treatment. The Devices do not satisfy CPT codes 93922, 93923, or 93924 because they do not perform an ABI.

The Devices also fail to satisfy Medicare reimbursement requirements because they use photoplethysmography, also known as photoelectric plethysmography, to generate a waveform. National Coverage Determination (“NCD”) 20.14 and the Local Coverage Determinations (“LCDs”) that incorporate it prohibit reimbursement for noninvasive vascular tests that use photoplethysmography because of concerns about accuracy and reproducibility.

### **FDA 510k Clearance of the Devices**

On February 12, 2010, the Food and Drug Administration (FDA) cleared Semler’s “FloChec Photoplethysmography Device.” In submissions to the FDA, the inventor compared FloChec to the predecessor device by describing it as “similar to the PPG [photoplethysmography] portion.” Under “Non-photo plethysmographic functions,” the inventor stated “none.”

Semler later changed the trade name from “FloChec Photoplethysmography Device” to “Flochech Device.”

On March 5, 2015, the FDA cleared QuantaFlo to “aid clinicians in the diagnosis and monitoring of Peripheral Arterial Disease.” During the approval process, Semler classified QuantaFlo as a “Hydraulic, pneumatic, or photoelectric plethysmograph[.]” Semler also represented to the FDA that there were no material changes between FloChec and QuantaFlo. During the 510k approval process, FDA employees told Semler that QuantaFlo uses photoplethysmography, did not perform an ABI, and could not be called a “digital ABI.”

### **Semler’s Marketing of Flochech and QuantaFlo**

Through the relevant time period, Semler represented to customers that Medicare has reimbursed other customers for tests performed using Flochee and QuantaFlo if they submitted the CPT codes 93922, 93923, and 93924. Semler made these representations in written reimbursement FAQs; trainings for customers and sales representatives; by email; in calls between Semler employees and customers; and through its distributor, Bard Peripheral Vascular, Inc. ("Bard").

Throughout the relevant time period, Semler received concerns from Bard, customers, and third-parties, including the American Medical Association and Society for Vascular Ultrasound, that tests performed using the Devices were not reimbursable because they do not satisfy the relevant CPT codes, NCD, and/or LCDs.

Semler continued to market the Devices as reimbursable through the end of 2024.

F. This Agreement is neither an admission of liability by Semler nor a concession by the United States that its claims are not well founded.

G. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. Semler shall pay to the United States \$29,750,000.00 ("Settlement Amount"), of which \$14,875,000.00 is restitution, and interest on the Settlement Amount at a rate of 4.25% per annum from April 28, 2025 ("Interest") no later than 14 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1, and as soon as feasible after receipt, the United States shall pay \$5,206,250 plus 17.5% of the Interest to Relator by electronic funds transfer ("Relator's Share").

3. Semler shall pay Relators \$390,000 no later than 7 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by undersigned Relators' counsel (the "Statutory Fees Payment"). Semler's payment of the Statutory Fees Payment will constitute full and complete satisfaction of their liability for Relators' statutory claim for reasonable attorneys' fees, expenses, and costs resulting from the Civil Action pursuant to 31 U.S.C. § 3730(d)(2).

4. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1, the United States releases Semler from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 7 below, and upon the United States' receipt of the Settlement Amount, plus Interest due under Paragraph 1, and Relators' receipt of the Statutory Fees Payment due under Paragraph 3, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Semler, as well as Semler's officers and directors, agents, servants, and employees and the assigns of each of them, and the successors and assigns of any of them, from any and all claims, whether in law or equity, whether known or unknown, that Relators have asserted, or could have asserted against Defendants as of the Effective Date of this Agreement, including but not limited to claims related to the Covered Conduct, Relators' or the United States's investigations or prosecutions thereof, Relators' original complaint(s) filed in this matter, and any civil monetary claim the Relators have on

behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. In consideration of the obligations of Semler in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Semler, and upon the United States' receipt of full payment of the Settlement Amount, plus Interest due under Paragraph 1, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Semler under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 10 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Semler from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;

- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the Relators' Share, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

9. Semler waives and shall not assert any defenses Semler may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole

or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

10. Semler fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Semler has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

11. Semler fully and finally releases Relators and their heirs, successors, attorneys, agents and assigns (the "Relator Releasees") from any and all claims, whether in law or equity, whether known or unknown, (including attorney's fees, costs, and expenses of every kind and however denominated) that Semler has asserted or could have asserted against the Relator Releasees as of the Effective Date of this Agreement, including but not limited to claims related to the Civil Action, the Covered Conduct, or Relators' or the United States' investigations or prosecutions thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Semler agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

13. Semler agrees to the following:



a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Semler, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Semler's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Semler makes to the United States pursuant to this Agreement and any payments that Semler may make to Relators, including costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 17.a.(6)

that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Semler.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Semler, and Semler shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Semler or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Semler further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Semler or any of their subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Semler agrees that the United States, at a minimum, shall be entitled to recoup from Semler any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The

United States reserves its rights to disagree with any calculations submitted by Semler or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Semler or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Semler's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

14. Semler agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Semler shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Semler further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Semler agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

17. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action only as to Semler pursuant to Rule 41(a)(1).

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Florida. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.


24. This Agreement is binding on Semler's successors, transferees, heirs, and assigns.


25. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

26. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

27. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

**THE UNITED STATES OF AMERICA**

DATED: 9/10/25 BY:   
KRISTEN M. ECHEMENDIA  
Senior Trial Counsel  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: 9/10/25 BY:   
MARTHA GLOVER  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice


DATED: 9/10/25 BY:   
KELLEN HOWARD ALLEN  
Assistant United States Attorney  
Middle District of Florida


DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
EDWARD WILSON Digitally signed by EDWARD WILSON  
Date: 2025.09.05 14:44:29 -04'00'  
SUSAN E. GILLIN  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**SEMLER SCIENTIFIC, INC.**

DATED: September 10, 2025 | 9:00 AM PDT BY:  DocuSigned by:  
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Semler Scientific, Inc.

DATED: 9/8/25 BY:   
AVI PERRY  
ALEX SPIRO  
JOHN (FRITZ) SCANLON  
Quinn Emanuel Urquhart & Sullivan, LLP  
Counsel for Semler Scientific, Inc.

DATED: 9/8/25 BY:   
MICHELE W. SARTORI  
Hogan Lovells US LLP  
Counsel for Semler Scientific, Inc.

**RELATORS**

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
ROBERT KANE

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
FRANKLIN W. WEST

DATED: \_\_\_\_\_ BY: \_\_\_\_\_  
DANIEL MILLER  
JONATHAN DE SANTIS  
Counsel for Relators Robert Kane and Franklin W. West

**SEMLER SCIENTIFIC, INC.**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
[NAME]  
Semler Scientific, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
AVI PERRY  
ALEX SPIRO  
JOHN (FRITZ) SCANLON  
Quinn Emanuel Urquhart & Sullivan, LLP  
Counsel for Semler Scientific, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
MICHELE W. SARTORI  
Hogan Lovells US LLP  
Counsel for Semler Scientific, Inc.

**RELATORS**


DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
ROBERT KANE

DATED: 9/5/25

BY:   
FRANKLIN W. WEST

DATED: 9/8/2025

BY:   
DANIEL MILLER  
JONATHAN DE SANTIS  
Counsel for Relators Robert Kane and Franklin W. West



SEMLER SCIENTIFIC, INC.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

[NAME]

Semler Scientific, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

AVI PERRY

ALEX SPIRO

JOHN (FRITZ) SCANLON

Quinn Emanuel Urquhart & Sullivan, LLP

Counsel for Semler Scientific, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

MICHELE W. SARTORI

Hogan Lovells US LLP

Counsel for Semler Scientific, Inc.

RELATORS

DATED: 9/4/25

BY: \_\_\_\_\_

  
ROBERT KANE

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

FRANKLIN W. WEST

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

DANIEL MILLER

JONATHAN DE SANTIS

Counsel for Relators Robert Kane and Franklin W. West