

**SUBMITTAL TO THE BOARD OF SUPERVISORS
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA**

226



SUBMITTAL DATE:
July 2, 2013

FROM: Department of Public Health

SUBJECT: Authorize the Department of Public Health to make purchases from the State Agreement with Masimo Corporation for Masimo Pronto Spot Check Pulse CO-Oximeter sensors.

RECOMMENDED MOTION: That the Board of Supervisors:

- 1) Authorize the Department of Public Health to make purchases from the State Agreement with Masimo Corporation for Masimo Pronto Spot Check Pulse CO-Oximeter sensors in the amount of \$137,476 for the period of July 1, 2013 through September 30, 2013; and,
- 2) Approve and direct the Auditor Controller to adjust the budget as specified in the Schedule A; and,
- 3) Authorize the Purchasing Agent, in accordance with Ordinance No. 459, to exercise renewal options for four additional years, based on the availability of fiscal grant funding not to exceed \$150,000 annually, and to procure the ancillary product from Masimo without obtaining competitive quotes that do not change the substantive terms of the State agreement.

PURCHASING & FLEET SERVICES: *Robert Howdyshell*, Director
 Departmental Concurrence
 FISCAL PROCEDURES APPROVED
 PAUL ANGULO, CPA, AUDITOR-CONTROLLER
 BY: *Samuel Wong* 5/27/13
 SAMUEL WONG

Susan D. Harrington
Susan Harrington, Director of Public Health

GH:nw

FINANCIAL DATA	Current F.Y. Total Cost:	\$ 137,476	In Current Year Budget:	No
	Current F.Y. Net County Cost:	\$ 0	Budget Adjustment:	Yes
	Annual Net County Cost:	\$ 0	For Fiscal Year:	13/14

SOURCE OF FUNDS: 100% Federal Funds	Positions To Be Deleted Per A-30	<input type="checkbox"/>
	Requires 4/5 Vote	<input checked="" type="checkbox"/>

C.E.O. RECOMMENDATION:

APPROVE

BY: *Debra Cournoyer*
Debra Cournoyer

County Executive Office Signature

Policy
 Policy
 Consent
 Consent

MINUTES OF THE BOARD OF SUPERVISORS

On motion of Supervisor Stone, seconded by Supervisor Ashley and duly carried by unanimous vote, IT WAS ORDERED that the above matter is approved as recommended.

Ayes: Jeffries, Tavaglione, Stone, Benoit and Ashley
Nays: None
Absent: None
Date: August 20, 2013

Kecia Harper-Ihem
 Clerk of the Board
 By: *Kecia Harper-Ihem*
 Deputy

Health, Purchasing, EO, Auditor

RECEIVED RIVERSIDE COUNTY

Prev. Agn. Ref.: 2/28/12, Item: 3.24 District: All Agenda Number:

3-65

ATTACHMENTS FILED

Form 11

Subject: Authorize the Department of Public Health to make purchases from the State Agreement with Masimo Corporation for Masimo Pronto Spot Check Pulse CO-Oximeter sensors.

Page 2

BACKGROUND:

The Department of Public Health has received \$160,000 in funds from California Women, Infants and Children Nutrition Program to participate in a pilot program for anemia screening of WIC participants. Funds will be used for the procurement of sensors used with the Masimo Pronto Spot Check Pulse CO-Oximeter. Participation in the pilot will allow WIC staff to perform a noninvasive anemia screening at the WIC sites to ensure all participants requiring documentation of anemia screening comply with the state requirement.

As specified in the state WIC April 19, 2013 WIC Local Agency Authority to Spend (ATS) letter, WIC local agencies participating in the pilot are authorized to procure sensors from Masimo, as the sole provider of the equipment.

PRICE REASONABLENESS:

For this pilot program, state WIC is using Masimo as a sole source. The state will provide DOPH forty-nine (49) Masimo Pronto Spot Check Pulse CO-Oximeters at no cost to the County. In addition, \$137,476 of the funds will be used to procure 212 Masimo sensors to be used with the Masimo Pronto Spot Check Pulse CO-Oximeters, with the capability of performing 400 tests per sensor at a cost of \$1.50 per test.

ATTACHMENT(S): Sole Source Justification

Form 11

Subject: Authorize the Department of Public Health to buy off the State Agreement with Masimo Corporation for Masimo Pronto Spot Check Pulse CO-Oximeter sensors.

Page 3

**SCHEDULE A
Department of Public Health
Budget Adjustment
Fiscal Year 2013/2014**

INCREASE IN APPROPRIATION:

10000-4200100000-HS100004-526960	Small Tools and Instruments	\$ 137,476
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TOTAL INCREASE IN APPROPRIATION:	\$ 137,476
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INCREASE IN ESTIMATED REVENUE:

10000-4200100000-HS100004-762040	Fed - Health Grants	\$ 137,476
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TOTAL INCREASE IN REVENUE:	\$ 137,476
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Date: May 13, 2013
From: Susan Harrington Department/Agency: Department of Public Health
To: Board of Supervisors/Purchasing Agent
Via: Purchasing Agent
Subject: Sole Source Procurement; Request for Masimo Corporation

The below information is provided in support of my Department requesting approval for a sole source. Outside of a duly declared emergency, the time to develop a statement of work or specifications is not in itself justification for sole source.

Supply/Service being requested: An Agreement with Masimo Corporation to procure sensors to be used with the Masimo Pronto Spot Check Pulse CO-Oximeter used as part of the State WIC funded anemia screening pilot program.

Supplier being requested: Masimo Corporation

Alternative suppliers that can or might be able to provide supply/service: Masimo is currently the sole manufacturer and distributor of FDA approved noninvasive hemoglobin technology, which is incorporated in the handheld Pronto device. DOPH has been funded by the State WIC program to participate in a pilot program for anemia screening using products manufactured and distributed solely by Masimo Corporation.

Extent of market search conducted: State WIC has identified Masimo as the sole manufacturer and distributor of FDA approved noninvasive hemoglobin technology, which is incorporated in the handheld Pronto device. In order to accept funding from State WIC to participate in this pilot program, participating agencies are required to use Masimo as a sole source per State WIC Authorize to Spend (ATS) letter dated April 19, 2013.

Unique features of the supply/service being requested from this supplier, which no alternative supplier can provide: Masimo Pronto Spot Check Pulse CO-Oximeter is unique in that it uses noninvasive hemoglobin technology. Masimo is currently the sole manufacturer and distributor of FDA approved noninvasive hemoglobin technology. This technology will allow WIC staff to perform noninvasive anemia screening of WIC participants.

Reasons why my department requires these unique features and what benefit will accrue to the county: The WIC program requires all local agencies to obtain documentation of anemia screening for prenatal women and children participating on WIC. Normally this documentation is provided by the WIC participant who obtains the documentation from their medical provider. Historically this has been a barrier to enrollment and/or continued participation on the WIC program, because the participant often finds it difficult to obtain the required documentation. This pilot will allow WIC staff to perform a noninvasive anemia screening at the WIC site, thus eliminating this barrier for our WIC participants.

Price Reasonableness including purchase price and any ongoing maintenance or ancillary costs from the supplier: As part of the pilot program, State WIC has negotiated with Masimo to provide DOPH with 49 Masimo Pronto Spot Check Pulse CO-Oximeters at no cost. DOPH will purchase the

sensors used with the device for anemia screening. These products are only available through Masimo. Product cost per test is \$1.50. As part of this pilot program, all cost associated with the product and program are 100% funded by State WIC.

Does moving forward on this product or service further obligate the county to future similar contractual arrangements or any ongoing costs affiliated with this single source? (Maintenance, support, or upgrades, if so, please explain). Yes, as required by the WIC program the County will continue to test clients annually. The County will have to purchase test strips for testing. Masimo will replace equipment at no charge to the County if the equipment become defective.

Period of Performance: July 1, 2013 through September 30, 2013

(Provide a defined period of performance. Please note multi-year terms require Board approval, unless renewable in one year increments and the Purchasing Agent approves the terms.)

Susan D. Harrington
Department Head Signature

6/27/13
Date

Purchasing Department Comments:

Approve

Approve with Condition/s

Disapprove

Not to exceed: \$137,476.00

One time

Annual Amount through _____

[Signature]
Purchasing Agent

6/24/2013
Date

14-025

Approval Number
(Reference on Purchasing Documents)

MINUTES OF THE BOARD OF SUPERVISORS
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA



3-44

On motion of Supervisor Tavaglione, seconded by Supervisor Stone and duly carried by unanimous vote, IT WAS ORDERED that the recommendation from Public Health regarding Authorizing of the Department to make purchases from the State Agreement with Masimo Corporation for Masimo Pronto Spot Check Pulse CO-Oximeter sensors is continued to Tuesday, August 20, 2013 at 9:00 a.m.

I hereby certify that the foregoing is a full true, and correct copy of an order made and entered on July 16, 2013 of Supervisors Minutes.

WITNESS my hand and the seal of the Board of Supervisors
Dated: July 16, 2013
Kecia Harper-Ihem, Clerk of the Board of Supervisors, in
and for the County of Riverside, State of California.

(seal)

By:  Deputy

AGENDA NO.
3-44

xc: Public Health, COB



JAY E. ORR
COUNTY EXECUTIVE OFFICER

**MEMORANDUM
COUNTY OF RIVERSIDE
EXECUTIVE OFFICE**

GEORGE A. JOHNSON
CHIEF ASSISTANT COUNTY EXECUTIVE OFFICER

ROB FIELD
ASSISTANT COUNTY EXECUTIVE OFFICER
ECONOMIC DEVELOPMENT AGENCY

BARBARA OLIVIER
ASSISTANT COUNTY EXECUTIVE OFFICER
HUMAN RESOURCES

ED CORSER
COUNTY FINANCE DIRECTOR

CHRISTOPHER HANS
CHIEF DEPUTY COUNTY EXECUTIVE OFFICER

TO: Kecia Harper-Ihem, COB
FROM: George A. Johnson, Chief Assistant CEO
DATE: July 15, 2013
RE: CONTINUANCE

Public Health is requesting that the following item be continued to August 20, 2013:

3.44 – Authorize the Department to make purchases from the State Agreement with Masimo Corporation for Masimo Pronto Spot check Pulse CO-Oximeter sensors.



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

RECEIVED APR 22 2013

RECEIVED APR 22 2013

April 19, 2013

Gayle Shockey Hoxter, M.P.H., R.D.
Chief of Nutrition Services
Riverside County Community Health Agency Department of Public Health
P.O. Box 7849
Riverside, CA 92513

Dear Ms. Shockey Hoxter,

I am writing to transmit a WIC Local Agency Authority to Spend (ATS) form (Enclosure A) authorizing funds for Other WIC Services as outlined in Exhibit A, Scope of Work, Provision 13 of the contract.

The maximum payable amount in your contract is a funding reserve for caseload and Other WIC Services. Approval to expend funding for Other WIC Services is granted by providing your local agency with the ATS form specifying the amount of reserve funding that may be spent, quantifying the services to be performed, and the performance outcomes expected. Other WIC Services may include breastfeeding promotion and education, participation in State-sponsored or approved committees and special projects.

Authority to Spend Form

- Not all local agencies will receive an ATS each month.
- Funds can only be spent on or after the effective date shown on the ATS form.
- Funds are either restricted or unrestricted and are authorized to reach agreed upon performance outcomes. "Restricted funds" cannot be spent for any purpose other than to meet performance objectives. "Unrestricted funds" are authorized to reach agreed upon performance outcomes and, when outcomes are met, any unused balances may be spent, on a discretionary basis, to pay for other services within the scope of the contract.
- Authorization to spend WIC funds does not constitute approval of individual procurements.



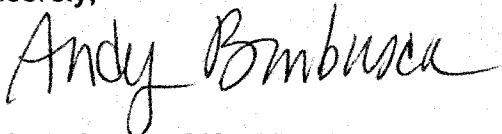
Women, Infants and Children (WIC) Program Division
3901 Lennane Drive, MS 8600, Sacramento, CA 95834
P.O. Box 997375, MS 8600, Sacramento, CA 95899-7375
(916) 928-8500 Internet Address: www.wicworks.ca.gov

Gayle Shockey Hoxter,
Page 2
April 19, 2013

Questions Regarding Performance Outcomes

- Questions regarding performance outcomes should be directed to the contact person listed on the back of the ATS form.
- If you have questions regarding this letter or the ATS process, please contact your Fiscal Advisor.

Sincerely,

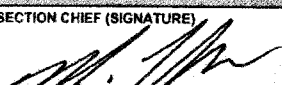


for Barbara Longo, MS, RD
Deputy Division Chief
Nutrition and Local Program Services

Enclosure

cc: Carely Linn
Fiscal Officer
P.O. Box 7849
Riverside, CA 92513

**WIC LOCAL AGENCY
AUTHORITY TO SPEND
Budget Period: 10/01/12 - 09/30/13**

LEGAL NAME (LOCAL WIC AGENCY) County of Riverside Health Services Agency	CONTRACT NUMBER 11-10485	AUTHORIZATION NUMBER 004	EFFECTIVE DATE February 1, 2013
FISCAL ADVISOR CONTACT Gema C. Monteiro		TELEPHONE NUMBER (916) 928-8651	
MAXIMUM PAYABLE AMOUNT:		\$18,754,000	
FUNDS AUTHORIZED FOR EXPENDITURE			
WIC BASE FUNDING:			
	<u>Previously Authorized</u>	<u>Currently Authorized</u>	
10/1/2012 Caseload Award	\$14,331,724		
OTHER WIC SERVICES:			
	<u>Authority To Spend Number</u>	<u>Previously Authorized</u>	<u>Currently Authorized</u>
The following funds are authorized to reach agreed upon performance outcomes and when met, any unspent balances may be used on a discretionary basis to pay for any Other WIC Services within the scope of the contract.			
002 WICHEALTH.ORG two subscriptions (53303)		\$403,700	
The following funds cannot be spent for any purpose other than to meet mutually agreed upon performance outcome(s) without advance approval in writing from the state. When costs are claimed for the following, expenditure detail must be provided on page two of the invoice.			
001 Task Force Committee (53303)		\$17,000	
001 BFPC Program Implementation - WIC BF PC Grant 2011-13 (53313)		\$900,000	
001 Regional Breastfeeding Liaison (RBL) Project (53303)		\$101,265	
002 Breast Pump Maintenance (53303)		\$4,000	
002 Education Committee (53303)		\$5,341	
002 Local Vendor Liaison (LVL) Roles & Responsibilities (53303)		\$246,720	
002 Regional training centers (53303)		\$78,523	
002 Academy For Participant Centered Leadership (APL) (53303)		\$11,300	
002 Training Committee (53303)		\$5,500	
003 RBL Health Care Provider Education Grant (53303)		\$7,500	
004 Anemia Screening Pilot (53303)			\$160,000
MAXIMUM PAYABLE BALANCE AVAILABLE FOR FUTURE AUTHORIZATION		\$2,481,427	
STATE WIC PROGRAM USE ONLY			
SECTION CHIEF (SIGNATURE) 			DATE 4/19/2013

LEGAL NAME (LOCAL WIC AGENCY) County of Riverside Health Services Agency		CONTRACT NUMBER 11-10485	AUTHORIZATION NUMBER 004	EFFECTIVE DATE February 1, 2013
Project Name	Amount	Restricted Fund (Yes/No)	PERFORMANCE OUTCOME	Contact Person (Name, Phone #, E-Mail)
WICHEALTH.ORG two subscriptions	\$ 403,700	No	The County of Riverside Health Services Agency will obtain and continue the subscriptions for the wichealth.org for years 2013 and 2014.	Giok Khoe (916) 928-8815 Giok.Khoe@cdph.ca.gov
Total Non-Restricted	\$ 403,700			
Task Force Committee	\$ 17,000	Yes	Task Force committee members must attend scheduled Task Force meetings in Sacramento; regional meetings in their service area; the spring and fall annual California WIC conferences; the NWA national conference and the NWA leadership conference. Members represent their constituents at the Task Force committee meetings and communicate outcomes to their constituents	Mariatu Johnson 916-928-8611 mariatu.johnson@cdph.ca.gov
BFPC Program Implementation - WIC BF PC Grant 2011-13	\$ 900,000	Yes	Implement or expand a new or current Breastfeeding Peer Counselor Program according to agency's approved RFA - WIC BFPC Grant 2011-2013	Kari Malone 916-928-8550 Kari.Malone@cdph.ca.gov
Regional Breastfeeding Liaison (RBL) Project	\$ 101,265	Yes	The funds will allow the WIC local agencies to continue to employ a dedicated staff member for breastfeeding outreach in the community as defined by the agency's RBL Plan of Action. The RBL Project aims to work towards closing the breastfeeding support gaps identified in the community assessments recently completed by local agencies.	Julie In 916-928-8683 Julie.In@cdph.ca.gov
Breast Pump Maintenance	\$ 4,000	Yes	Maintain electric breast pumps in working order and purchase WIC allowable breastfeeding and promotion support items.	Thuy Pham 916-928-8639 thuy.pham@cdph.ca.gov
Education Committee	\$ 5,341	Yes	Selected local agency staff attend up to four (4) meetings events per year.	Judy Sheldon 916-928-8759 Judy.sheldon@cdph.ca.gov
Local Vendor Liaison (LVL) Roles & Responsibilities	\$ 246,720	Yes	Conduct LVL activities that are outlined in chapter two of the CMB and in the WIC Local Vendor Liaison Roles and Responsibilities document. Local agencies will receive funding based on the rate of \$60 per vendor (all store types) x 16 hours/year. Allowable expenses covered in the funding rate include: personnel, IT support, materials, training, travel, communications, facilities and equipment. Additionally, agencies with 20 stores or less will receive a base funding to assist with limited resources. The TA performance standard is 90% and includes LVLs conducting at minimum one TA visit per assigned vendor within each quarter and recording all visits in the state tracking system on monthly basis. State WIC will assist local agencies unable to perform LVL duties or meet the performance standard by coordinating redistribution of vendors and funding to neighboring agencies.	Reema El-Murr 916-928-8599 reema.el-murr@cdph.ca.gov
Regional training centers	\$ 78,523	Yes	Provide training room facility, site logistics, and appropriate equipment such as computers, internet access, ISIS, copiers, screens, and other training equipment necessary to conduct WIC IT training, breastfeeding/breastfeeding peer counseling trainings, various local agency training and vendor training. Establish and maintain a booking priority system to ensure up to 130 days within FFY 2013, excluding Mondays and Fridays, for state agency use.	Reema El-Murr 916-928-8599 reema.el-murr@cdph.ca.gov

LEGAL NAME (LOCAL WIC AGENCY) County of Riverside Health Services Agency			CONTRACT NUMBER 11-10485	AUTHORIZATION NUMBER 004	EFFECTIVE DATE February 1, 2013
Academy For Participant Centered Leadership (APL)	\$ 11,300	Yes	These funds are to be used for travel expenses necessary to attend the APL workshops and costs related to the implementation of a platinum project. Agencies that have other funds available for travel may elect to use all of these funds for implementing their platinum projects. Note: Use of these funds for a platinum project is contingent upon the submission and approval of a completed project plan prior to spending the funds.	Delfina Shelomenseff 916-928-8541 Delfina.Shelomenseff@cdph.ca.gov	
Training Committee	\$ 5,500	Yes	Participate in up to four (4) committee meetings and one pre-approved conference. Communicate on regular basis throughout FFY 2012 by phone or electronically to conduct work on projects, follow-up on progress toward meeting committee goals, and report on performance outcomes.	Annalisa Sherman 916-928-8858 asherman@cdph.ca.gov	
RBL Health Care Provider Education Grant	\$ 7,500	Yes	These funds will be used for the RBLs to provide evidence-based breastfeeding education to health care providers (HCPs).	Toni Piechota Toni.Piechota@cdph.ca.gov 916-928-8761	
Anemia Screening Pilot	\$ 160,000	Yes	Funds to be used to purchase anemia blood screening sensor devices, batteries, alcohol wipes and protective cases. All agencies must follow the Anemia Screening Pilot protocol. The anemia screening device reads and displays the participant's hemoglobin level. Low hemoglobin level may indicate anemia as a result of a nutrient deficiency. WIC Local Agencies are authorized to procure devices from Masimo Americas, Inc. as the sole provider of the equipment.	Sharon Streifling 916-928-8523 Sharon.Streifling@cdph.ca.gov	
Total Restricted	\$ 1,537,149				



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

Date: April 25, 2013

To: Local WIC Agencies Participating in the 2013 Anemia
Screen Pilot Project

Subject: Masimo Pronto 7 Sole Source Procurement

I am writing to notify you that the California Women, Infants and Children (WIC) Nutrition Program has an approved pilot study using the Masimo Pronto 7 device and screening accessories to be used for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin and total hemoglobin concentration.

The Masimo Pronto 7 is the only device of this kind approved by the Food and Drug Administration (FDA) for use in clinical and non-clinical settings. Furthermore, the Masimo Pronto 7 device is the only device of this kind approved for use on both adult and pediatric individuals. (See Attached)

CA WIC has entered into an agreement with Masimo Corporation to provide the devices to participating local WIC agencies at an agreed upon price of \$1.50 per test. The Masimo Corporation has agreed to take full responsibility for the maintenance of the devices and will replace at no charge nonfunctioning devices at any time during the pilot project.

CA WIC has provided funding to cover the cost of the tests and supplies for the remainder of FFY 2013. Additional funding will be provided to all participating local WIC agencies in FFY 2014, beginning October 1, 2013.

Please contact me at (916) 928-8870 if you have any further questions or need additional information.

Sincerely,

Barbara Longo, M.S., R.D.

Deputy Division Chief

Nutrition and Local Program Services

Women, Infants and Children (WIC) Program Division



Women, Infants and Children (WIC) Program
3901 Lennane Drive MS 8600 Sacramento, CA 95834
P.O. Box 997375 MS 8600 Sacramento, CA 95899-7375
(916) 928-8500 Internet Address: www.wicworks.ca.gov



May 1, 2013

To Whom It May Concern,

I would like to confirm that Masimo Corporation is currently the sole manufacturer/distributor of FDA approved noninvasive hemoglobin technology; which is incorporated in the handheld Pronto device.

Please feel free to contact me if you have additional questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrew H. Jones', written in a cursive style.

Andrew Jones
Vice President, US Alternate Care Masimo Corp.
40 Parker
Irvine, CA 92168



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

Mr. Anil Bhalani
Director of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

DEC 30 2011

Re: K111403
Trade/Device Name: Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and
Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, GLY
Dated: December 22, 2011
Received: December 28, 2011

Dear Mr. Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Bhalani

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories

Statement of Indications for Use:

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SP02), pulse rate, and total hemoglobin concentration (SpHb). The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals, in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, home, clinics, physician offices and ambulatory surgery centers).

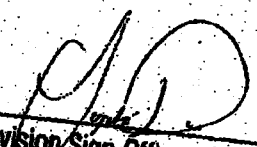
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of _____

510(k) Number: K111403

K111403

DEC 30 2011

510(k) SUMMARY

Applicant: Masimo Corporation
40 Parker
Irvine, CA 92618
949-297-7000
FAX 949-297-7592

Company Contact: Anil Bhalani
Director of Regulatory affairs

Date Summary Prepared: November 10, 2011

Trade Name: Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories

Common Name: Oximeter

Classification Name/ Product Code: Oximeter (21CFR 870.2700/ Product Code: DQA)

Predicate Device: K100403- Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories (Pronto-7)

Device Description

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories include the noninvasive technology spot check of measurement for functional saturation of arterial oxygen hemoglobin (SpO₂), pulse rate and total hemoglobin concentration (SpHb), which is based on the same technology of the predicate device. This submission introduces two new sensor sizes (medium and small) and an optional Maximum Sensitivity Mode that extends the detection range for SpHb.

Intended Use/ Indications for Use

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO₂), pulse rate, and total hemoglobin concentration (SpHb). The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals, in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, home, clinics, physician offices, and ambulatory surgery centers).

Technology Comparison

The Fundamental Scientific Technology of the previously cleared Pronto-7 device and Sensor and that of the Pronto-7 device and sensors is the same.

Device	Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories	
	K100403	K111403 (Subject Device)
Display Range	Saturation (SpO ₂): 0-100% Pulse Rate: 30-250 bpm Total Hemoglobin (SpHb): 0-25 g/dL Perfusion Index (PI): 0.02-20%	Same
Accuracy Adults and Pediatrics (> 30kg)	SpO ₂ : 70-100±2%	Same
	Pulse Rate: 30-250±3 bpm	Same
	Normal Sensitivity Mode: SpHb: 6-18 g/dl ±1 g/dL	Normal Sensitivity Mode: Same Maximum Sensitivity Mode: SpHb: 4.5-20 g/dl ±1.1 g/dL
Resolution	SpO ₂ : 1%; Pulse Rate: 1 bpm, SpHb: 0.1 g/dL	Same
AC Power	Voltage Input: 100-240 VAC, 50-60 Hz; Max Power Consumption: 15 VA	Same
Batteries	Rechargeable lithium polymer battery	Same
Temperature	Operating: 41 to 104°F (5 to 40°C) Storage: -40° to 158°F (-40 to 70°C)	Same
Relative Humidity	5 to 95% non-condensing	Same
Operating Altitude	500 to 1,060 mbar; -1,000 to 18,000 ft (-304 to 5,486m)	Same
Alarm	System Failure; Low Battery Alarm	Same
Display and Indicators	SpO ₂ (%); Pulse Rate (bpm); SpHb (g/dl); Perfusion Index (%); Pleth Waveform; Sensor Status; Status Messages; Battery Status	Same
Connection/ Output	Wireless: Bluetooth 2.0; Wi-Fi b/g; Flash Memory: Micro SD card slot	Same
Earphone jack	Connection for standard 3.5 mm earphone jack	Same
EMC/Electrical Safety Compliance	EN 60601-1 -2, Class B IEC 60601-1, UL 60601-1, CAN/CSA STD C22.2, Internally Powered, AC Power Class 2, Compliance Type BF- Applied Part, IPX1, Class 2	Same
Mode of Operation	Spot Check	Same

Performance Data Summary

SpO₂ accuracy has been validated in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation. Pronto-7 measurements on volunteers induced hypoxia in the range of 70-100% SpO₂ are compared against a laboratory CO-Oximeter and ECG monitor. SpHb accuracy has been validated with (arterial/ venous) blood from healthy adult male and female volunteers and on patients with light to dark skin pigmentation in the ranges of 6-18 g/dl SpHb (Normal Sensitivity Mode) and 4.5-20 g/dl SpHb (Maximum Sensitivity Mode), with Pronto-7 measurements compared against a laboratory CO-Oximeter. Pulse rate accuracy has been validated on healthy adult male and female volunteers and on patients with light to dark skin pigmentation in the range of 40-110 bpm. The variation in these studies equals plus or minus one standard deviation encompasses 68% of the population.

Results: The studies were performed in accordance with ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. The studies resulted in SpO₂ accuracy (rms) of $\pm 2\%$, pulse rate accuracy (rms) of ± 3 bpm, and SpHb accuracy (rms) of ± 1 g/dl (Normal Sensitivity Mode) and ± 1.1 g/dl (Maximum Sensitivity Mode).

Non-Clinical Data Summary

The Pronto-7 complies with the voluntary standards as detailed in this submission. Laboratory testing for biocompatibility, safety and environmental was conducted to verify that the Pronto 7 met all design specifications and is considered equivalent to the predicate device.

Conclusions

The information in this 510(k) submission demonstrates that the Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are substantially equivalent to the predicate device with respect to safety and effectiveness.