July 14, 2021

Shenzhen Kaiyan Medical Co Ltd
℅ Alain Dijkstra
Manager
SHENZHEN KAIYAN MEDICAL CO LTD.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510006
China

Re: K202390
Trade/Device Name: Aduro Light Beauty Mask
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS, OLP, ILY
Dated: August 14, 2020
Received: August 21, 2020

Dear Alain Dijkstra:

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 post-marketing 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,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202390

Device Name
Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B)

Indications for Use *(Describe)*

For MK-66O, MK-66USBO, MK-02O:
The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.

For MK-66USBA, MK-02A:
The Aduro Light Beauty Mask (Model: MK-66USBA, MK-02A) is intended to emit light in the blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

For MK-66USBB, MK-02B:
The Aduro Light Beauty Mask (Model: MK-66USBB, MK-02B) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.

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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Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD
Subject Device: Aduro Light Beauty Mask
Document Name: 510(k) Summary

510(k) Summary of K202390

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

1. Submitter's Information

Company Name: SHENZHEN KAIYAN MEDICAL CO LTD
Establishment Registration Number: 3011644607
Address: 40A Fuxin Road, Fuyong Subdistrict, BaoAn District, Shenzhen Guangdong, China
Contact Person (including title): Alain Dijkstra (CEO)
Tel: 0755-82129361
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E-mail: alaindijkstra@kaiyanmedical.com

Application Correspondent:

Contact Person: Alain Dijkstra
SHENZHEN KAIYAN MEDICAL CO LTD.
Address: 40A Fuxin Road, Fuyong Subdistrict, BaoAn District, Shenzhen Guangdong, China
Tel: 0755-82129361
Email: regulation@kaiyanmedical.com

2. Subject Device Information

Type of 510(k): Traditional
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
Trade Name: Aduro Light Beauty Mask
Model Name: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulatory Class: II

3. Predicate Device Information

Predicate device	Predicate device 1	Predicate device 2	Predicate device 3
Sponsor	Galactic Beauty, LLC	Beijing ADSS Development Co., Ltd.	ISMART Marketing Svcs Ltd
Device Name and Model	MMSphere	LED Therapy Device	FaceLITE
510(k) Number	K190443	K192295	K191629
Classification Name	Light Based Over-The-Counter Acne Treatment / Light Based Over the Counter Wrinkle Reduction	Light Based Over-The-Counter Acne Treatment / Light Based over the Counter Wrinkle Reduction	Light Based Over-The-Counter Wrinkle Reduction
Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Product Code	OLP, OHS	OLP, OHS	OHS
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	II	II	II

4. Device Description

For MK-66O, MK-66USBO, MK-02O:

The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) is a facemask-shaped device, which makes use of specific light spectral characteristics and directly applies light onto the face skin surface. The Aduro Light Beauty Mask can emit light with two different center wavelengths. The blue light (465nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. Red light (640nm) is intended to improve the appearance of wrinkles. There are a total of 66 LEDs to provide power intensity of about 30mw/cm^2.

The user wears the mask on their face for the treatment, and the device will shut down automatically after finishing a 10-minute treatment.

For MK-66USBA, MK-02A:

The Aduro Light Beauty Mask (Model: MK-66USBA, MK-02A) is a facemask-shaped device, which makes use of specific light spectral characteristics and directly applies specified light onto the face skin surface. The Aduro Light Beauty Mask can emit the blue light (465nm) which is intended to help reducing the appearance of mild to moderate inflammatory acne. There are a total of 66 LEDs to provide power intensity of about 30mw/cm^2.

The user wears the mask on their face for the treatment, and the device will shut down automatically after finishing a 10-minute treatment.

For MK-66USBB, MK-02B:
The Aduro Light Beauty Mask (Model: MK-66USBB, MK-02B) is a facemask-shaped device, which makes use of specific light spectral characteristics and directly applies specified light onto the face skin surface. The Aduro Light Beauty Mask can emit the red light (640nm) which is intended to improve the appearance of wrinkles. There are a total 66 LEDs to provide power intensity of about 30mw/cm^2.
The user wears the mask on their face for the treatment, and the device will shut down automatically after finishing a 10-minute treatment.

5. Intended Use / Indications for Use

For MK-66O, MK-66USBO, MK-02O:
The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.

For MK-66USBA, MK-02A:
The Aduro Light Beauty Mask (Model: MK-66USBA, MK-02A) is intended to emit light in the blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

For MK-66USBB, MK-02B:
The Aduro Light Beauty Mask (Model: MK-66USBB, MK-02B) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.

6. Non-clinical Testing

Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B) has been evaluated for safety and performance by testing as follows:

Standards No.	Standard Title	Version	Date
ES 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012	07/09/2014

Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD
Subject Device: Aduro Light Beauty Mask
Document Name: 510(k) Summary

Standards No.	Standard Title	Version	Date
IEC 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Edition 2.0 2015-01	06/27/2016
IEC 60601-2-57	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	Edition 1.0 2011-01	03/16/2012
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Edition 4.0 2014-02	09/17/2018
IEC 62366-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	Edition 1.0 2017-02	12/23/2019
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	12/23/2016

Standards No.	Standard Title	Version	Date
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition 2010-08-01	07/26/2016

7. Comparison to the predicate devices

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2 (Primary device)	Predicate Device 3	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD.	Galactic Beauty, LLC	Beijing ADSS Development Co., Ltd.	ISMART Marketing Svcs Ltd	--
Trade Name	Aduro Light Beauty Mask	MMSphere	LED Therapy Device	FaceLITE	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)	Light Based Over The Counter Wrinkle Reduction	Light Based Over-The-Counter Powered Light Based Laser For Acne/Light Based over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	--
510(k) Number	K202390	K190443	K192295	K191629	--
Product Code	OLP, OHS	OLP, OHS	OLP, OHS	OHS	SE
Intended Use / Indications for Use	The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate	The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne. The device	The faceLITE LED mask is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2 (Primary device)	Predicate Device 3	Remark
	and/or mild to moderate acne.	acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	is indicated for adults only.		
Wavelengths	Red: 640nm±10nm Blue: 465nm±10nm	Red: 605nm Blue: 465nm Amber: 625nm	Red: 630nm±5nm Blue: 415nm±5nm	Red: 630nm+/-10nm NIR: 830nm+/-10nm	SE
Power supply	For model MK-66O, MK-66USBO: 3.7Vdc 2600mAh Lithium battery Adapter for charging only: Input: 100-240Vac; Output: 5Vdc, 2A. For model MK-02O: 3.7Vdc 2600mAh Lithium battery	Not publicly available	5.V DC 2.0 A Powered by direct plug-in adapter: Input 100-240V AC, 50/60 Hz, 0.5A Max., Output 5.0V DC 2.0A	Rechargeable Lithium ion polymer battery	SE
Irradiance source	LEDs	LEDs	LEDs	LEDs	SE
Treatment time	10minutes/day, 3 times per week	20 mins / day	3-5 minutes each treatment	10 minutes each treatment	SE See Note
Power Density	30mw/cm^2	Red: 2.45mW/cm^2 Blue: 1.33mW/cm^2	Red light: 80 mW/cm^2±10% Blue light: 50 mW/cm^2±10%	30mw/cm^2 total	SE
Location for Use	Face	Face	Face	Face	SE
Environment of Use	OTC	OTC	OTC	OTC	SE
Safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-2-57	SE
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1, ISO 10993-5, ISO 10993-10	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD.	Galactic Beauty, LLC	Beijing ADSS Development Co., Ltd.	JOHNSON & JOHNSON CONSUMER INC.	--
Trade Name	Aduro Light Beauty Mask	MMSphere	LED Therapy Device	Neutrogena Light Therapy Acne Mask+	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne (OLP)	Light Based Over The Counter Wrinkle Reduction	Light Based Over-The-Counter Powered Light Based Laser For Acne/Light Based over the Counter Wrinkle Reduction	Over the Counter powered Light Based Laser for Acne	--
510(k) Number	K202390	K190443	K192295	K180847	--
Product Code	OLP	OHS, OLP	OHS, OLP	OLP	SE
Intended Use / Indications for Use	The Aduro Light Beauty Mask (Model: MK-66USBA, MK-02A) is intended to emit light in the	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the	The red light is intended for the treatment of periorbital wrinkles and the blue light is	The Light Therapy Acne Mask + is intended to emit energy in the red and	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
	blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	intended for the treatment of the mild to moderate inflammatory acne. The device is indicated for adults only.	blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	
Wavelengths	Blue: 465nm±10nm	Red: 605nm Blue: 465nm Amber: 625nm	Red: 630nm±5nm Blue: 415nm±5nm	Red: 620-640nm Blue: 425-450nm	SE
Power supply	For model MK-66USBA: 3.7Vdc 2600mAh Lithium battery Adapter for charging only: Input: 100-240Vac; Output: 5Vdc, 2A. For model MK-02A: 3.7Vdc 2600mAh Lithium battery	Not publicly available	5.V DC 2.0 A Powered by direct plug-in adapter: Input 100-240V AC, 50/60 Hz, 0.5A Max., Output 5.0V DC 2.0A	Ni-MH Batteries	SE
Irradiance source	LEDs	LEDs	LEDs	LEDs	SE
Treatment time	10minutes/day, 3 times per week	20 mins / day	3-5 minutes each time	600 seconds	SE See Note
Power Density	30mw/cm^2	Red: 2.45mW/cm^2 Blue: 1.33mW/cm^2	Red light: 80 mW/cm^2±10% Blue light: 50 mW/cm^2±10%	30mw/cm^2 total	SE
Location for Use	Face	Face	Face	Face	SE
Environment of Use	OTC	OTC	OTC	Home (OTC)	SE
Safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-	SE

Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD
Subject Device: Aduro Light Beauty Mask
Document Name: 510(k) Summary

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
				2-57	
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD.	Galactic Beauty, LLC	Beijing ADSS Development Co., Ltd.	ISMART Marketing Svcs Ltd	--
Trade Name	Aduro Light Beauty Mask	MMSphere	LED Therapy Device	FaceLITE	--
Classification Name	Light Based Over-The Counter Wrinkle Reduction (OHS)	Light Based Over The Counter Wrinkle Reduction	Light Based Over-The-Counter Powered Light Based Laser For Acne/Light Based over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	--
510(k) Number	K202390	K190443	K192295	K191629	--

Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD
Subject Device: Aduro Light Beauty Mask
Document Name: 510(k) Summary

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
Product Code	OHS	OHS, OLP	OHS, OLP	OHS	SE
Intended Use / Indications for Use	The Aduro Light Beauty Mask (Model: MK-66USBB, MK-02B) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	MMSphere™ Light Therapy Device emits energy in the red, blue and amber regions of the spectrum, specifically indicated to treat wrinkles and/or mild to moderate acne. The MMSphere™ is designed to be used for 20 minute treatments three to seven times per week.	The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne. The device is indicated for adults only.	The faceLITE LED mask is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	SE
Wavelengths	Red: 640nm±10nm	Red: 605nm Blue: 465nm Amber: 625nm	Red: 630nm±5nm Blue: 415nm±5nm	Red: 630nm+/-10nm NIR: 830nm+/-10nm	SE
Power supply	For model MK-66USBB: 3.7Vdc 2600mAh Lithium battery Adapter for charging only: Input: 100-240Vac; Output: 5Vdc, 2A. For model MK-02B: 3.7Vdc 2600mAh Lithium battery	Not publicly available	5.V DC 2.0 A Powered by direct plug-in adapter: Input 100-240V AC, 50/60 Hz, 0.5A Max., Output 5.0V DC 2.0A	Rechargeable Lithium ion polymer battery	SE
Irradiance source	LEDs	LEDs	LEDs	LEDs	SE
Treatment time	10minutes/day, 3 times per week	20 mins / day	3-5 minutes each time	600 seconds	SE See Note
Power Density	30mw/cm^2	Red: 2.45mW/cm^2 Blue: 1.33mW/cm^2	Red light: 80 mW/cm^2±10% Blue light: 50 mW/cm^2±10%	30mw/cm^2 total	SE
Location for Use	Face	Face	Face	Face	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Primary device)	Remark
Environment of Use	OTC	OTC	OTC	OTC	SE
Safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IE C 60601-1-11, IEC 60601-2-57	SE
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1, ISO 10993-5, ISO 10993-10	SE

Note: The treatment time of the subject device is different than the predicate devices. However, it is considered to be within an acceptable range and does not raise concerns regarding safety and effectiveness, and new clinical studies were not considered to be necessary for the subject device.

8. Conclusion：

After an analysis of intended use, performance, safety, and technological characteristics of the subject device, the sponsor believes that it has demonstrated that the subject device can be operated safely and effectively for the proposed indications for use. When compared to the predicate devices, the subject device does not raise new issues of safety or effectiveness. Therefore, the sponsor believes that the subject Aduro Light Beauty Mask models listed above are substantially equivalent to the predicate devices.

Date that summary was prepared: July 8, 2021