

FDA

Fiscal Year 2023

CERTIFICATION OF REGISTRATION

This certifies that:

Name: BIOEVOPEAK CO., LTD.

Add: Rm. 2014, Bldg. 3, LigaoguojiHuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong, 250100, CHINA

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

Registration/FEI Number: 3020526004

Owner/Operator Number: 10083884

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration. ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Dec.29, 2022

Date of expiration: Dec.31, 2023

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

1312 17th Street Suite 692 Denver, CO 80202

TEL:303-800-0162 info@abmed.com.cn

FDA

Listing No	Premarket Submission NO.	Code	Device Name
D462801	510(k) exempt	DOP	MASS SPECTROMETER, CLINICAL USE,COD Analyzer,Conductivity Meters, Dissolved Oxygen Meters, Ion Meters, Multiparameter Meters, ORP Meters, Benchtop PH Meter, Pocket PH Meter, Salinity Meters, TDS Meters, Titrator, Water Hardness Meters, Chlorine Meter
D462814	510(k) exempt	JJN	APPARATUS, ELECTROPHORESIS, FOR CLINICAL USE,Electrophoresis Cell, Nucleic Acid Sequencing,Electrophoresis Cell, Vertical Type, Electrophoresis Tank, 2-dimensional, Electrophoresis Tank, Isoelectric Focusing Type, Electrophoresis Tank, Semi-dry Transfer Type, Horizontal Electrophoresis Cell, Inner Core of Electrophoresis Tank, Sequencing Electrophoresis Tank, Electrophoresis Power Supply, Electrophoresis System, Gel Imaging System, Transilluminator,
D462815	510(k) exempt	JJQ	COLORIMETER, PHOTOMETER, SPECTROPHOTOMETER FOR CLINICAL USE,Turbidity Meters, Colorimeter, Gloss Meter, Hazemeter, Melting Point Apparatus, Polarimeters, ABBE Refractometer, Automatic Refractometer, Portable Refractometer, Atomic Absorption Spectrophotometer, Flame Photometer, Flame Photometer, Grating Spectrophotometer, Micro-Volume UV/VIS Spectrophotometer, NIR Spectrophotometer, Scanning Spectrophotometer, Single Beam Spectrophotometer, UV Visible Spectrophotometer
D462811	510(k) exempt	IDL	MICROTOME, ACCESSORIES,Digital Pathology Slide Scanner, Paraffin Dispenser, Paraffin Trimmer, Slide Cabinet,Tissue Flotation Water Bath, Tissue Processor

FDA

Listing No	Premarket Submission NO.	Code	Device Name
D462826	510(k) exempt	LXG	EQUIPMENT, LABORATORY, GENERAL PURPOSE, LABELED OR PROMOTED FOR A SPECIFIC MEDICAL USE, Isolator, IVC Cage, IVC System, Analytical Balances, Moisture Balances, Platform Scales, Precision Balances, Semi-Micro Balance, Acid and Alkali Storage Cabinet, Chemical Safety Cabinet, Gas Cylinder Storage Cabinet, Hospital Furniture, Bullet Ice Maker, automatic type, Snow Ice Maker, automatic, CO2 Incubators, CO2 Stacked Thermostatic Oscillator, Constant Temp. & Humidity Chamber, Cooling Biochemical Incubator, BOD Incubator, Cooling Biochemical Incubator, Microbiology Cooling Incubator, Egg Incubator, Heating Incubator, Plant Growth Chamber, Shaking Incubators, Glassware Washers, Ultrasonic Cleaners, Biological Safety Cabinets, Dispensing Booth, Fume Hood, Laminar Flow Cabinet, Liquid Dispenser, Liquid Vacuum Aspiration, Pipettes, Density Meter, Viscosity Baths, Digital Viscometer, Total Organic Carbon Analyzer, Microplate Reader, Microplate Washer, Block Heater, In Situ Hybridization, Thermal Cycler, Clarification Tester, Transparency Tester, Disintegration Testers, Gelatin Testing, Tablet Friability Testers, Tablet Hardness Testers, Tablet Thickness Testers, Medicine Stability Testing Chamber, Homogenizers, Fully Automatic Sample Digestion System, Graphite Digester, Microwave Digestion System, Microwave Digestion/Extraction System, Microwave Sample Preparation System, Sample Concentrators,

FDA

Listing No	Premarket Submission NO.	Code	Device Name
D462823	510(k) exempt	KSQ	DEVICE, BLOOD MIXING AND BLOOD WEIGHING,Blood Collection Monitor,Blood Plasma Extractor
D462427	510(k) exempt	KZJ	DEVICE, GAS GENERATING,Anaerobic Incubators,Anaerobic Jar,
D462824	510(k) exempt	KZA	DEVICE, VEIN LOCATION, LIQUID CRYSTAL,Vein Finder,
D462821	510(k) exempt	JTQ	BATH, INCUBATORS/WATER, ALL,Thermostatic Magnetic Stirring Bath.Water Bath Oscillator, Thermostatic,Water Bath Shaker, TFT Display,Water Bath,Water Bath,Water bath, WB8T
D462822	510(k) exempt	KSE	REFRIGERATOR, FREEZER, BLOOD STORAGE,Freezers, Refrigerator,Blood Bank Refrigerator,Car Refrigerator,Combined Refrigerator & Freezer,Corpse Refrigerator,Portable Refrigerator
D462812	510(k) exempt	IDP	MICROTOME, CRYOSTAT, Flootation Workstation, Cryostat Microtome, Fast Freezing Machine, Fully Automated Microtome, Manual Rotary Microtome, Rotary Microtome, Semi-Automated Rotary Microtome, Vibrating Microtome
D462813	510(k) exempt	JDY	EVACUATOR, VAPOR, CEMENT MONOMER,Filter Funnel ManifoldsChemistry-design Diaphragm Pump,Diaphragm Pump,Diaphragm Vacuum Pump,Water Circulating Vacuum Pump
D462810	510(k) exempt	IBJ	LIGHT, MICROSCOPE,Biological Microscope,Digital Microscope,Fluorescence Microscope,Inverted Microscope,Metallurgical Microscope,Polarizing Microscope,Stereoscopic Microscope,Teaching Microscope

FDA

Listing No	Premarket Submission NO.	Code	Device Name
D462820	510(k) exempt	JRS	PURIFIER, WATER (ABSORPTION, DEIONIZATION, MEMBRANE FILTER, REVERSE OSMOSIS),Water Distiller,Double-stage RO Pure Water Machine,Ultra-pure Water Machine
D462818	510(k) exempt	JRQ	SHAKER/STIRRER,Combination Stirring Hotplates,Conventional Hotplates,Heating Mantles,Magnetic Stirrers,Overhead Stirrer,Roller Mixer,Rotary Mixer,Vortex Mixer,Linear Shaker,Orbital Shaker,Rocker Shaker,
D462819	510(k) exempt	JRR	REGULATOR, TEMPERATURE,Cooling Circulator,Low Temperature Circulator,Recirculating Chiller,Refrigerated and Heating Circulator,20L Industrial Digital Rotary Evaporator,Dynamic Temperature Control System,Vacuum Controller,
D462816	510(k) exempt	JQC	CENTRIFUGES (MICRO, ULTRA, REFRIGERATED) FOR CLINICAL USE,Clinical Centrifuge, PRP ,Fat Transplantation Centrifuge,Gel Card Centrifuge,Microplate Centrifuge, PCR,Oil Test Centrifuge,PRP Centrifuge,High Speed Centrifuges,High Speed Refrigerated Centrifuges,Low Speed Centrifuges,Low Speed Refrigerated Centrifuges,Mini Centrifuges,Multi Purpose Centrifuges
D462817	510(k) exempt	JRJ	UNIT, DRYING,Dual Convection Oven,Dual Purpose (Oven/Incubator),Forced-Air Drying Oven,Natural Convection Oven,Vacuum Oven,
D462809	510(k) exempt	FLH	WASHER OF BODY WASTE RECEPTACLES, Eye Washer
D462825	510(k) exempt	LDM	INSTRUMENTATION, HIGH PRESSURE LIQUID CHROMATOGRAPHY, Liquid Chromatograph

FDA

Listing No	Premarket Submission NO.	Code	Device Name
D474045	510(k) exempt	GKB	DEVICE, AUTOMATED SEDIMENTATION RATE - ESR Analyzer
D474049	Enforcement Discretion	CHL	Electrode measurement, blood-gases (pco2, po2) and blood ph - Blood Gas Analyzer
D474046	510(k) exempt	KQO	AUTOMATED URINALYSIS SYSTEM - Urine Analyzer
D474047	510(k) exempt	GGN	Plasma, coagulation control - Coagulation Analyzer
D474048	510(k) exempt	JJP	ELECTRODE, ION SELECTIVE (NON-SPECIFIED) - Electrolyte Analyzer
D474050	Enforcement Discretion	FAZ	SYSTEM, CRYOSURGICAL, LIQUID NITROGEN, FOR UROLOGY - Liquid Nitrogen Tank