UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

REGION III

STATEMENT OF BASIS

B. BRAUN MEDICAL, INC.

ALLENTOWN, PENNSYLVANIA

EPA ID NO. PAD982679169

I. Introduction

A. Facility Name

The United States Environmental Protection Agency (EPA) has prepared this Statement of Basis (SB) for the B. Braun Medical, Inc. Facility (herein after referred to as "B. Braun," "Facility" or "Site") located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109. Please refer to Figure 1 for a Site Location Map.

The Facility is subject to the Corrective Action program under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, and the Hazardous and Solid Waste Amendments (HSWA) of 1984, 42 U.S.C. Sections 6901 to 6992k. The Corrective Action program is designed to ensure that certain facilities subject to RCRA have investigated and cleaned up any releases of hazardous waste and hazardous constituents that have occurred at their property.

Information on the Corrective Action program as well as a fact sheet for the Facility can be found by navigating http://www.epa.gov/reg3wcmd/correctiveaction.htm.

B. Proposed Decision

EPA's review of available information indicates that there are no unaddressed releases of hazardous waste or hazardous constituents from the Facility. Based on that assessment, our proposed decision is that no further investigation or cleanup is required. EPA's proposed decision meets the criteria for *Complete without Controls*, established in EPA's RCRA guidance titled: *Final Guidance on Completion of Corrective Action Activities at RCRA Facilities*. This guidance can be found in the Federal Register / Vol. 68, No. 37 / Tuesday, February 25, 2003 / Notices [FRL – 7454-7] pages 8757 to 8764. EPA has determined that its proposed decision is protective of human health and the environment and that no further corrective action or land use controls are necessary at this time.

C. Public Participation

Interested persons are invited to comment on EPA's proposed decision. The public comment period will last thirty (30) calendar days from the date that notice is published in a local newspaper. Comments may be submitted by mail, fax, e-mail, or phone to Ms. Jeanna R. Henry at the address listed below. EPA will hold a public meeting to discuss this proposed decision upon request. Requests for a public meeting should be made to Ms. Jeanna R. Henry at the address listed below.

EPA has developed an Administrative Record (AR) for this proposed decision which contains all information considered by EPA during the process. The AR is available at the following location:

U.S. EPA Region III
1650 Arch Street
Philadelphia, PA 19103
Contact: Ms. Jeanna R. Henry (3LC30)
Phone: (215) 814-2820
Fax: (215) 814 - 3113
Email: henry.jeannar@epa.gov

EPA encourages interested persons to participate in the remedy selection process by reviewing this SB and documents contained in the AR. The AR contains the complete information that EPA reviewed prior to this proposed decision.

EPA will address all significant comments received during the public comment period. If EPA determines that new information or public comments warrant a modification to the proposed decision, EPA will modify the proposed decision or select other alternatives based on such new information and/or public comments. EPA will approve its final decision in a document entitled the Final Decision and Response to Comments (FDRTC). Any person who comments on the decision will automatically receive a copy of the FDRTC. Any other person wishing to receive a copy of the FDRTC may obtain one by contacting Ms. Jeanna R. Henry.

II. Facility Background

B. Braun is a privately-owned health care company that provides healthcare products, services and educational programs that enhance the care and safety of patients and healthcare professionals in the fields of drug delivery, IV therapy, pain control, clinical nutrition, dialysis and vascular intervention. B. Braun's products and services are used in hospitals, outpatient surgery centers and in the home care setting. The B. Braun Facility located at 901 Marcon Boulevard in Hanover Township, Lehigh County, Pennsylvania, manufactures, prepares and sterilizes plastic disposable medical devices, such as valves, adapters, piercing devices, stopcocks, infusion pumps and systems, syringes, cannulae, regional anesthesia, balloon catheters, fluid administration systems, interventional products, and safety products.

The Facility is situated on 29.32-acres in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The Site is surrounded on all sides by office complex buildings, and an airport tarmac for the Lehigh Valley International Airport is located to the immediate northwest. The property was owned by Burron Medical, Inc. from 1984 to 1994. B. Braun purchased the property in 1994 and is the current owner of the Site. Structures on the Site include the original 285,000 square foot building (i.e., Main Building) which was constructed in 1985, in addition to a 75,000 square foot building (i.e., Specialty Product Manufacturing (SPM)) constructed in 2009. Currently, B. Braun operates as a subsidiary of B. Braun Melsungen AG.

III. Summary of Environmental History

A. Hazardous Waste Notification

Burron Medical, Inc. filed an initial Notification of Hazardous Waste Activity with EPA in June 1990. The initial notification identified Burron as a Small Quantity Generator (SQG, less than 1,000 kilograms (kg) per month) of hazardous waste. As a result, Burron Medical, Inc. was issued the EPA Identification Number PAD982679169. On May 5, 1997, B. Braun submitted a subsequent Notification of Hazardous Waste Activity to EPA. The subsequent notification identified the Facility's name change from Burron Medical, Inc. to B. Braun and updated the Facility's (i.e., B. Braun) generator status to a Large Quantity Generator (LQG, greater than 1,000 kg per month) of hazardous waste. The EPA Hazardous Waste Codes identified on the subsequent notification included: D001 (ignitable), D002 (corrosive), D010 (selenium), D011 (silver), F002 (halogenated solvents), and F003 (non-halogenated solvents).

On April 30, 1997, B. Braun applied for a Permit By Rule (PBR) with the Pennsylvania Department of Environmental Protection (PADEP) for its neutralization process of Ethylene Glycol (25 Pa Code 265.433 – Neutralization Treatment Units). On June 6, 1997, PADEP notified B. Braun of the Department's determination that the Facility's neutralization unit (referred to as a captive wastewater treatment unit by PADEP) qualifies for PBR.

On May, 2, 2011, Michael Jr. Baker, Inc. (Baker) conducted an Environmental Indicator (EI) Inspection of B. Braun, on behalf of EPA. The findings of the EI Inspection are documented in a September 2011 EI Inspection Report for B. Braun Medical, Inc., prepared by Baker. Information gathered during the EI Inspection identified generation of the following hazardous wastes by B. Braun: D001 (spent isopropyl alcohol (IPA), ignitable), D008 (lead), D009, (mercury), D010 (selenium), D039 (tetrachloroethylene (PCE)), and F002 (spent methylene chloride (MeCl), spent halogenated solvents).

B. Description of Solid Waste Management Units

EPA has identified the following Solid Waste Management Units (SWMUs) at the Facility based on the Agency's review of available information.

1. SWMU No. 1 – Elementary Neutralization Unit

The Facility's elementary neutralization unit (ENU) operates under a PBR in accordance with the federally authorized Commonwealth of Pennsylvania Hazardous Waste Regulations (PaHWR). The ENU is located within the southern portion of the Main Building (refer to Figure 2 – Facility Layout) in the Deoxx Room, which are secure and require card access. The ENU consists of a 3,000-gallon aboveground storage tank (AST), two towers, and a reaction tank. The unit is completely enclosed with cinder block walls on three sides, an approximately 1.5 feet tall concrete curb on the forth side, and a concrete floor.

The ENU was installed and began operation in 1985, and is used to neutralize ethylene glycol process wastewater generated by the Facility's closed-loop ethylene oxide sterilization

emissions control system (i.e., deoxx scrubber system). Prior to neutralization using sodium hydroxide, the Facility's ethylene glycol process wastewater is hazardous for the characteristic of corrosivity (EPA Hazardous Waste Code D002). Following neutralization, the Facility's process wastewater is shipped off-site to be reused in the manufacture of antifreeze. There have been no documented releases or violations on record relative to the Facility's ENU.

2. SWMU No. 2 – Former Hazardous Waste Accumulation Area

The Facility's Former Hazardous Waste Accumulation Area was located on the southeast side of the Facility, just outside of the Main Building. Between 1989 and 2002, the Facility used this area for the accumulation of hazardous waste with the EPA Hazardous Waste Codes D001 (ignitable), D002 (corrosive), D035 (methyl ethyl ketone), F002 (spent halogenated solvents), F003 (spent non-halogenated solvents), and P042 (epinephrine waste). The Former Hazardous Waste Accumulation Area consisted of a hazardous material storage shed constructed with secondary containment that was completely enclosed and located within a fenced area to restrict access. There are no documented releases for this unit.

3. SWMU No. 3 – Current Hazardous Waste Accumulation Area

The Facility's current hazardous waste accumulation area is located at the northeast end of the property adjacent to the Main Building. The area is surrounded by a six-foot high chain link fence with two gated and locked entrances. Two completely enclosed hazardous material storage sheds equipped with secondary containment are present within the accumulation area. Both of the units are approximately 10-feet by 20-feet in size.

The southern unit is used for the storage of raw materials in 55-gallons drums, including various grades of IPA, MeCl, tetrahydrofuran (THF), cyclohexane, and MTM, a mixture (pre-mixed) of MeCl and THF. The northern unit is used to store both hazardous and non-hazardous wastes in 55-gallon drums. Hazardous wastes accumulate in this area include the EPA Hazardous Waste Codes D001 (ignitable), D002 (corrosive), D035 (methyl ethyl ketone), F002 (spent halogenated solvents), F003 (spent non-halogenated solvents), and P042 (epinephrine waste). All raw materials and wastes stored in the Current Hazardous Waste Accumulation Area are placed inside of the storage sheds; no raw materials or waste materials are stored outside. There have been no documented releases from the Facility's current hazardous waste accumulation area.

4. SWMU No. 4 – Empty Ethylene Oxide Drum Storage Area

The Facility receives ethylene oxide (EtO), a colorless, ignitable, high reactive gas, in pressurized drums. The raw material drums of ethylene oxide are stored in the Ethylene Oxide Room (or Gas Room), which is located within the Main Building, adjacent to the deoxx scrubber system. The EtO is used to sterilize medical devices in the Facility's eight (8) humidified rooms (i.e., sterilization units). Following sterilization, the medical devices are aerated in the aeration room to remove residual EtO. The EtO is directed to the deoxx scrubber system, which converts the EtO into ethylene glycol and water, which is stored in the 3,000-gallon AST associated with the Facility's ENU (SWMU No. 1). EtO is also directed to the catalytic oxidizer located on the

west side of the Facility, which converts EtO to carbon dioxide and water. The catalytic oxidizer is equipped with a heat recovery unit, and the heat is directed back into the aeration unit. Once "empty" (not to be confused with the term "RCRA Empty"), the EtO drums are stored in a fenced and locked storage area located outside of the EtO room until they are returned to the vendor as a hazardous material.

5. SWMU No. 5 – Emergency Catch Basin Underground Storage Tank

The Emergency Catch Basin Underground Storage Tank (UST), also known as Tank 001, is located on the northwest side of the Facility. Tank 001 is a registered UST (Facility ID No. 39-37781) and is regulated under the PADEP's UST Program. Tank 001 was installed in April 1999, and is constructed of double-walled steel with a plastic jacket. The piping associated with Tank 001 is gravity fed and constructed of single-walled PVC plastic. Tank 001 acts as an emergency catch basin and is set up to receive ethylene glycol that is spilled or released to the floor drains located inside each sterilization unit, throughout the areas where EtO is used, and from the Facility's deoxx scrubber system.

As indicated by B. Braun during Bakers' May 2011 EI Inspection, approximately 200-400 gallons of liquid are removed from the UST routinely by the same company that empties the 3,000-gallon AST associated with the Facility's ENU, which contains an ethylene glycol and water mixture. The contents of Tank 001 and the 3,000-gallon AST are removed at the same time and comingled for off-site shipment to be reused in the manufacture of antifreeze. As a regulated UST, Tank 001 is equipped with an interstitial sensor that monitors the UST's interstitial space for leaks, in addition to an overfill alarm, both of which are monitored via an automatic tank gauging system (ATG).

Tank 001 was last inspected for compliance with PADEP's UST Program on May 31, 2011 and no problems were noted. A review of past inspections shows there are no documented releases from Tank 001.

C. Summary of Environmental Investigations and Remediation

There have been no known or documented releases to Site soils or groundwater relative to B. Braun's operations. Therefore, no detailed site-specific geologic or hydrogeologic studies have been conducted at the Site within a regulatory framework, nor is there evidence available to presume that such work is warranted. EPA's determination that no further investigation is warranted is primarily based on the historical land use and manufacturing operations conducted at the Site, the Facility's compliance history with respect to environmental laws, and the nature and quantity of the hazardous wastes managed by the Facility.

The Site was first developed in 1985, and since that time, the Facility has only been used for the manufacture of healthcare products. As a LQG of hazardous waste and owner/operator of a registered UST, the Facility has also been the subject of regular compliance inspections by PADEP's hazardous waste and UST programs. A review of the PADEP compliance inspections shows that such inspections only resulted in minor waste management (i.e., improperly labeled drum) and paperwork violations. In addition to inspections conducted by PADEP, as a

manufacturer of healthcare products, the Facility is also audited regularly by the Food and Drug Administration (FDA).

With respect to the hazardous wastes generated by the Facility, the largest hazardous waste stream generated and managed by the Facility is ethylene glycol process wastewater which is only hazardous for the characteristic of corrosivity (i.e., pH of wastewater is less than 2.0). This waste stream is managed in aboveground units (tanks, reactors) and piping, all of which are visible and situated above an impermeable surface (concrete). In the event of a release or spill of ethylene glycol process wastewater, such a release or spill would be identified immediately and cleaned up. The other hazardous waste streams generated by the Facility are managed in containers on top of impermeable surfaces (concrete, pavement) or in hazardous material storage sheds equipped with secondary containment. Such storage sheds are also situated on top of impermeable surfaces.

D. Evaluation of Exposure Pathways

1. Direct Contact with Soils Pathway

EPA has concluded that Site soils do not represent a viable potential exposure pathway to contaminants by human and ecological receptors. There have been no known/documented releases to Site soils relative to B. Braun's operations and Site soils are not known or reasonably suspected to be contaminated. All manufacturing operations and waste management activities take place within the Facility buildings or in areas that Site soils are covered with impermeable surfaces, such as, concrete slabs and asphalt paving.

2. Direct Contact with Groundwater Pathway

EPA has concluded that groundwater at the Site does not represent a viable potential exposure pathway to contaminants by human and ecological receptors. There have been no known/documented releases to Site soils and/or groundwater relative to B. Braun's operations, and groundwater at the Site is not known or reasonably suspected to be contaminated. In addition, water and sewer are provided to the Facility and surrounding area by the Catasauqua Municipal Water Works. According to the Catasauqua Borough's 2010 Annual Drinking Water Quality Report, drinking water is derived entirely from three (3) municipally owned and operated groundwater wells located within 1,200 feet of the water plant located at Walnut and St. Johns Streets in Catasauqua. The wells range in depth from 141 below ground surface (bgs) to 235 feet bgs. The water plant is located approximately 1.6 miles northwest of the Facility.

Furthermore, in accordance with Chapter 235, Article III, Section 235-13.L., "all subdivisions and land developments located within the Borough of Catasauqua shall be served with public water and sanitary sewer facilities unless the Commission determines that such facilities are not required or that suitable alternate facilities meeting the requirements of the Pennsylvania Department of Environmental Protection shall be provided."

3. Soil and Groundwater Indoor Air Pathways

As previously stated above, there have been no known/documented releases to Site soils or groundwater relative to B. Braun's operations, and Site soils and groundwater are not known or reasonably suspected to be contaminated. All manufacturing operations and waste management activities take place within the Facility buildings or in areas that Site soils and groundwater are covered with impermeable surfaces, such as, concrete slabs and asphalt paving. Therefore, EPA has concluded that Site soils and groundwater do not represent a viable potential exposure pathway to contaminants by human and ecological receptors.

E. Summary of EPA's Proposed Decision

EPA has concluded that the soil and groundwater quality at the Facility does not pose any potential for harm to human health or the environment and no further action or controls are necessary for the Facility. This determination is based on a review of all available records, in addition to information collected during a May 2, 2011 site visit, which show that there have been no reportable releases; there is no evidence of current soil or groundwater contamination above EPA's Regional Screening Levels (RSLs) and PADEP's Residential Medium Specific Concentrations (MSCs); and, there is no on-going site remediation or monitoring efforts at this Facility.

Date: 12/8/11

Abraham Ferdas, Director
Land and Chemicals Division
US EPA, Region III

Figure 1

Facility Location Map

B. Braun Medical, Inc.

Allentown, Pennsylvania

Source: Google, 2010

200 0 100 200
1 inch = 200 ft.

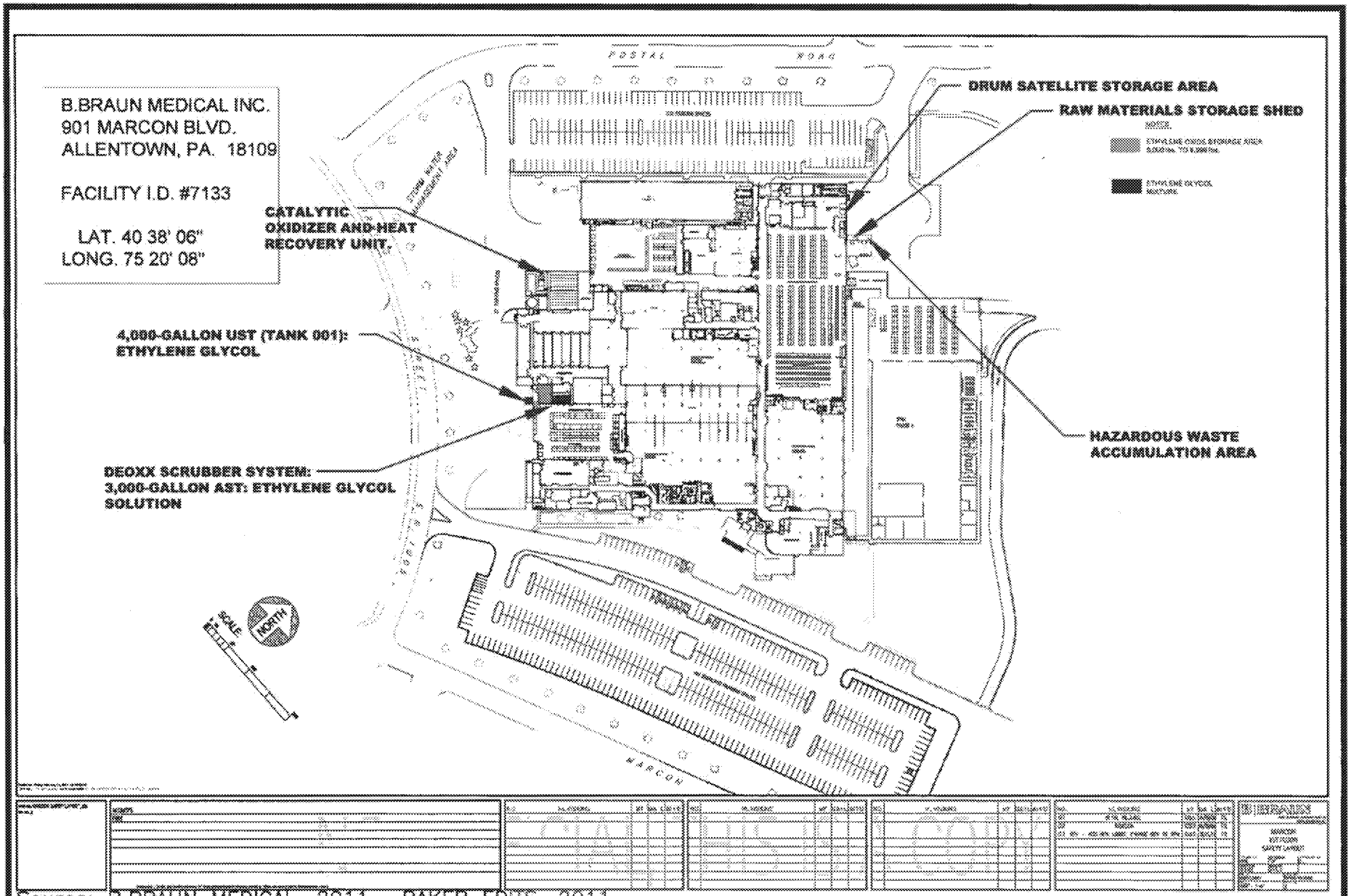
SCALE: 1" = 200'	DATE: JULY 2011	Baker MICHAEL BAKER JR., INC. MOON TOWNSHIP, PENNSYLVANIA	FIGURE 1 FACILITY LOCATION MAP B. BRAUN MEDICAL, INC. ALLENTOWN, PENNSYLVANIA
S.O. NO.: 120674	FILE: 120674-BRAUN-01		
DSN/DWN: KT/RRR	CHK: SF		

Figure 2

Facility Layout

B. Braun Medical, Inc.

Allentown, Pennsylvania



Source: B.BRAUN MEDICAL, 2011 BAKER EDITS. 2011

SCALE: NOT TO SCALE	DATE: JULY 2011	MICHAEL BAKER JR., INC.
S.O. NO.: 120674	FILE: 120674_BRAUN_02	MOON TOWNSHIP, PENNSYLVANIA
DSN/DWN: KT/RRR	CHK: SF	

FIGURE 2
FACILITY LAYOUT
B. BRAUN MEDICAL, INC.
ALLENTOWN, PENNSYLVANIA