COMPANY Materials to be provided to NIH Grantees as part of the Grant Program
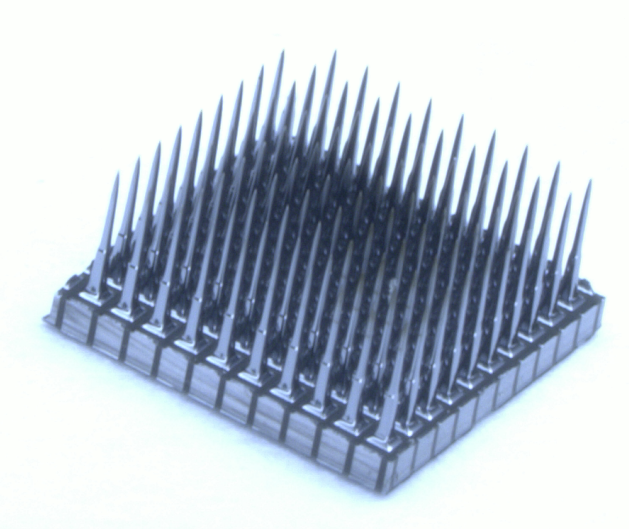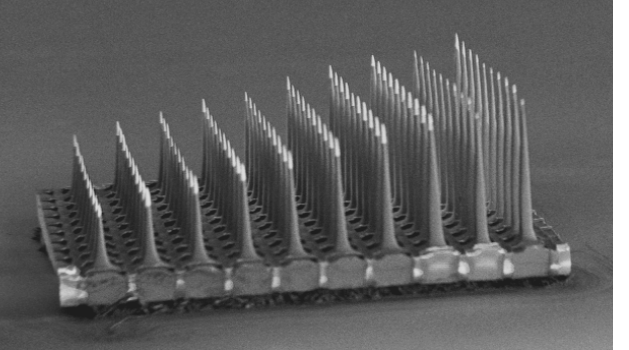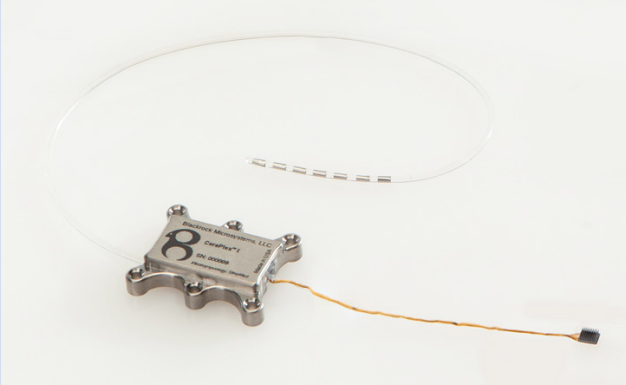
Product /	Applications and Unique Features	Regulatory Status
NeuroPort™ Electrode Array - Silicon intracortical microelectrode array	 • 96-channel microelectrode array designed for spike and local-field potentials (LFP) recording from cortex • Fixed geometry for precise location of electrode contacts. • 400 μm electrode pitch, 4 mm x 4 mm overall size • Customizable electrode lengths and configurations • The Utah Electrode Array is the neural interface powering several brain-machine interface applications where human patients control external devices such as robotic arms and computers. • Platinum and sputtered iridium oxide electrodes	510(k) approval for studies of less than 30 days. IDE approved clinical studies of chronic recording and stimulation for more than 30 days.
Utah Slanted Electrode Array - Silicon intrafascicular microelectrode array for peripheral nerve applications.	 • 96-channel microelectrode array for highly selective stimulation and recording in peripheral nerves • Varied electrode length for full coverage of nerve cross-section • Fixed geometry ideal for nerve mapping studies • High selectivity within nerve fascicles for precise control of multiple different innervation targets of the implanted nerve • Platinum and sputtered iridium oxide electrodes	Not cleared for clinical use by FDA, but can be used under IRB or IDE guidance for research studies.

NeuroPort Biopotential Signal Processing System - Real-time data acquisition and processing system for up to 512 channels	• Data acquisition system for full-bandwidth neural recording, experiment control, signal analysis and display • Highly customizable through Matlab/C++ APIs • Real-time data access ideal for closed-loop applications such and brain-machine interfaces	510(k)
Cervello Elite - 128 or 256 channel combined video EEG and microelectrode data acquisition system	• Full-featured NeuroPort data acquisition system combined with clinical video EEG software • Allows clinical long-term epilepsy monitoring to be combined, in a single system, with research objectives such as single-unit recording	510(k)
CerePlex I - 128	 • Fully implantable 128-ch amplifier for full-bandwidth recordings of spike and local field potentials (LFPs). • Can be interfaced to any front-end electrode such as the Utah Electrode Array, ECoG grids, µECoG grids, depth electrodes, etc • On-board digitization and multiplexing reduces transcutaneous lead to a single 11-contact pigtail connector to maximize patient comfort and minimize infection risk	Not cleared for clinical use by FDA, but can be used under IRB or IDE guidance for research studies.
CereStim - 96 channel stimulator for micro and macro electrodes	• Software controlled stimulation for up to 96 channels • Available for both micro and macro electrodes • Highly flexible stimulation control through Matlab/C++ API	Not cleared for clinical use by FDA, but can be used under IRB or IDE guidance for research studies.
Electrode Inserter system	• Pneumatic insertion system for Utah Electrode Array and Utah Slanted Electrode Array for cortical and peripheral nerve applications	510(k)
Splitter box	• Head stage allowing the Blackrock NeuroPort Biopotential Signal Processing System to share electrode signals with 3rd party acquisition systems	510(k)

Auxiliary Support	Description
Engineering Expertise	• Product development using FDA Design Control Processes • Microfabrication of silicon- and polymer-based devices • Custom electrode array architectures for neural recording and stimulation • Analog and digital circuit design

	• Embedded systems • Custom ASIC development • Hermetic packaging • Wireless data transmission • Custom software development for experiment control, data acquisition, analysis and display • Custom neural recording headstages and adapters
Regulatory Assistance	• Rights of reference to leverage existing data from cleared and pre-clinical devices towards new IDE submissions • Support and expertise in IDE submissions • Support and expertise in IRB submissions
Data Repository	• Centralized repository for data sharing • Physiological data • Analysis code

510(k) Clearances	Number
Neuroport™ Cortical Microelectrode Array Systems	K042384
Neuroport™ Signal Processor Systems	K042626
Neuroport™ Biopotential Signal Processing System	K090957
Neuroport™ Electrode SIROF	K110010
Neuroport™ Electrode	K070272

Additional Support

Blackrock will provide technical support assistance towards the successful execution of any joint projects under the SPARC program. Blackrock may also provide software and hardware engineering support as required for the project.