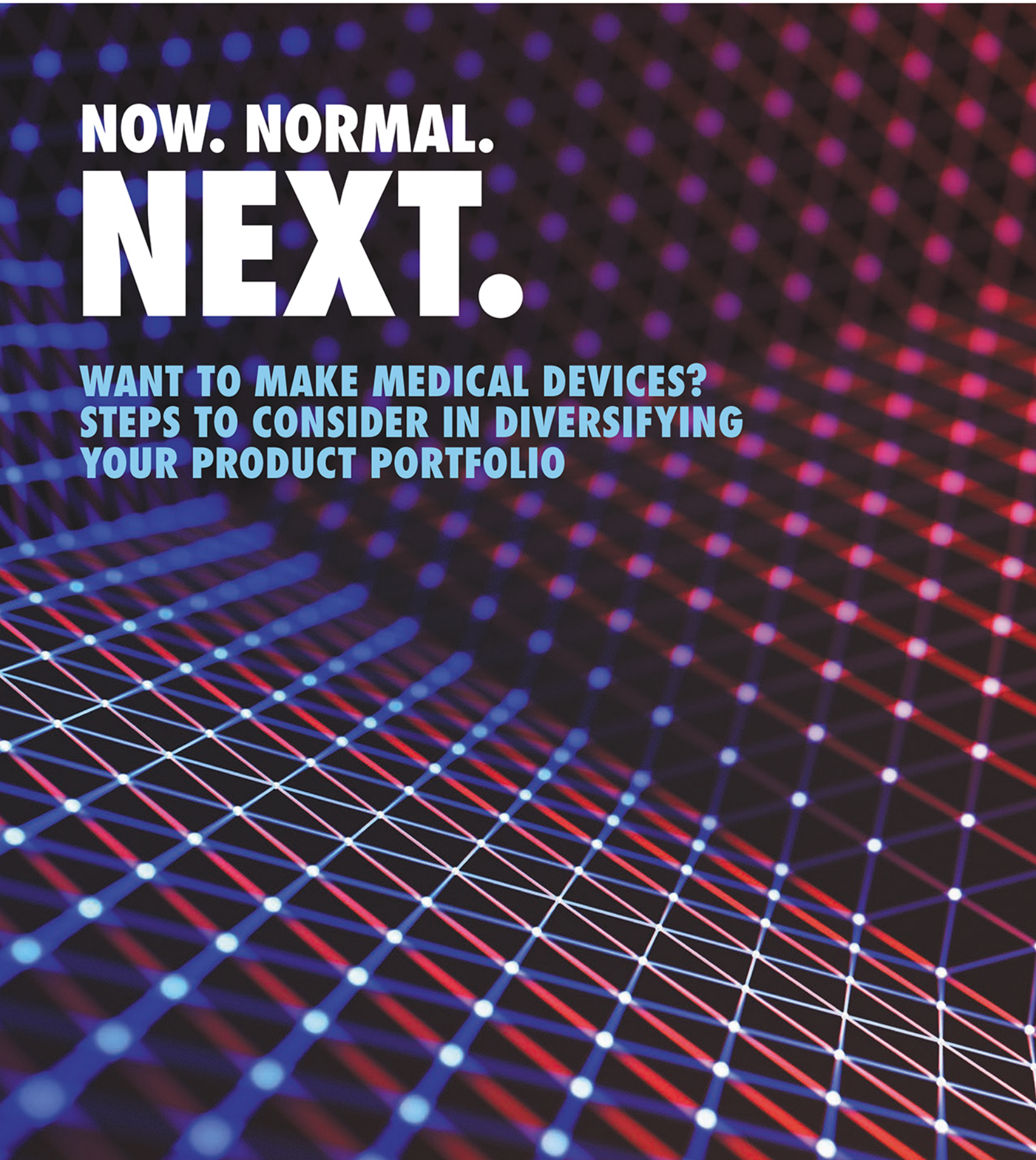
Morgan Lewis



COVID-19 has changed and will likely forever change the products we use in our daily lives.

From daily use of face masks to help slow the spread of COVID-19, to thermal imaging systems that measure our temperature before entering a retail establishment, place of employment, or school, there has been and will continue to be an increased need for these products and technologies as we embrace the new normal. In fact, certain jurisdictions are requiring certain products (e.g., masks, thermal scanners/temperature screeners) be in place as a condition of operating within the jurisdiction. Moreover, the demand for such medical products will increase as fall approaches and jurisdictions consider the resumption of in-person schooling.

Technological advances in diagnostic testing, clinical decision support software, personal protective equipment (PPE) manufacturing, and remote patient monitoring technologies will take center stage as the world emerges in the post COVID-19 economy.

Nontraditional medical device manufacturers that have engineering/product capabilities and manufacturing capacity can take advantage of these growth opportunities in the COVID-19 marketplace to diversify their revenue streams and expand their customer base. For example:

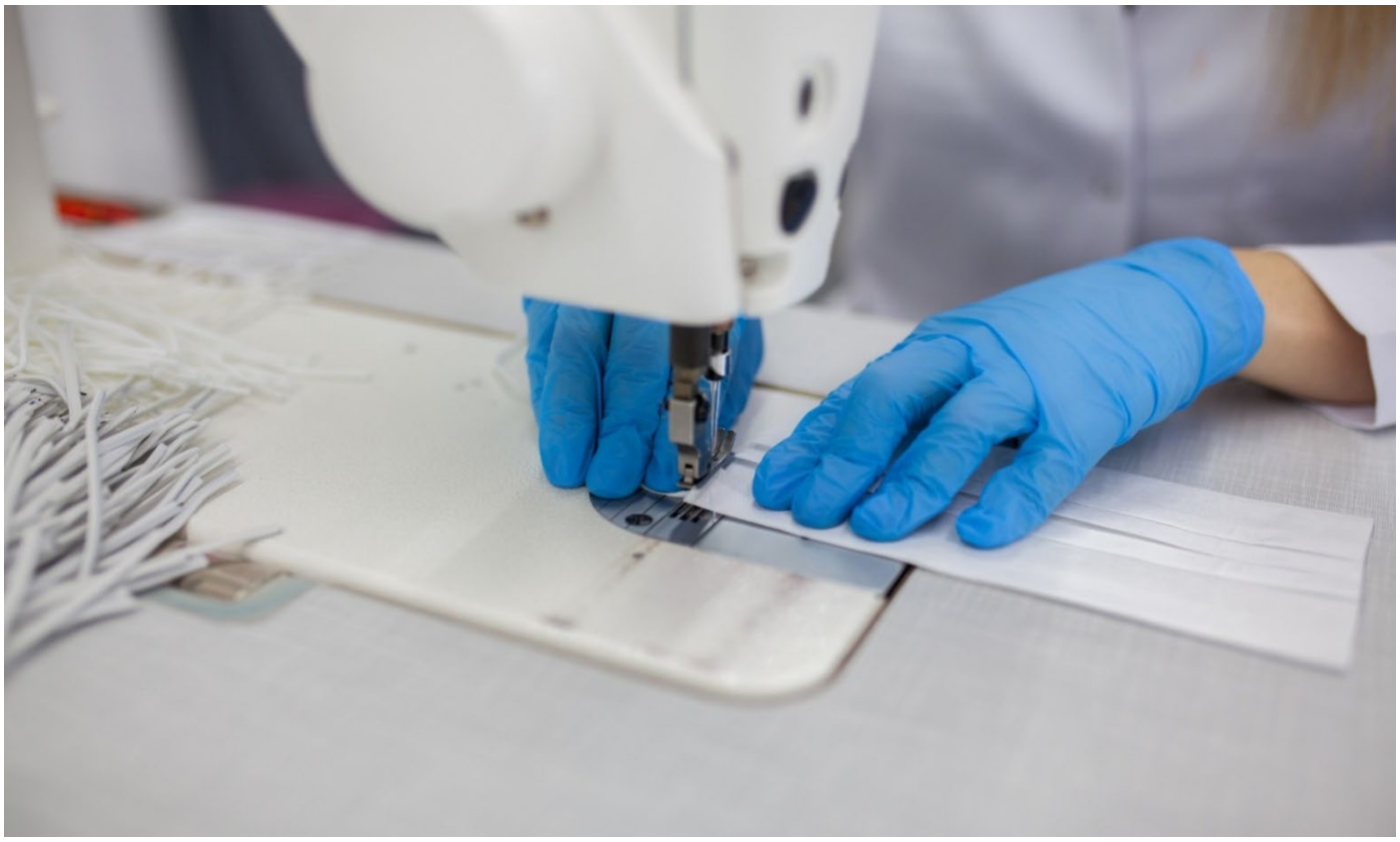
- Air purification and ventilation system manufacturers can re-position their products for use in helping to prevent the spread of COVID-19 (especially for use in businesses that are reopening);
- Furniture manufacturers can produce hospital beds, stretchers, and mattresses to help meet increased demand of goods caused by COVID-19 hospitalizations;
- Soft drink bottlers can use their manufacturing lines to produce test tubes to collect patient samples for COVID-19 diagnostic testing;
- Nonmedical labs can use their expertise to develop diagnostic tests and test components to screen patients for COVID-19;
- Software developers can develop systems (potentially using AI-based technology) to model COVID-19 spread;
- Thermal imaging manufacturers can market their products to screen individuals (e.g., customers, employees) for fevers, a COVID-19 symptom;
- Software developers can develop apps for use in evaluating the likelihood of exposure to COVID-19;
- Clothing manufacturers can transform production lines to make face masks or other PPE; and
- Manufacturers with 3D printers can make swabs to be used in collecting samples for COVID-19 testing.

There are a number of laws and regulations that govern the COVID-19 product marketplace. Government agencies around the world, however, have taken a number of actions to help market entrants looking to make device products to help with COVID-19 relief efforts. For example:

- In a June 1, 2020 speech, US Food and Drug Administration (FDA) Commissioner Dr. Stephen Hahn indicated that the FDA has and will continue to work with companies that don't regularly make medical products (but want to pitch in) so that there is an adequate supply of medical products as the United States continues to reopen.
- In Europe, national governments have been encouraged by the European Commission to lower the administrative burden on placing medical devices and PPE on the market.
- In China, the country is adjusting its regulatory requirements and procedures on medical devices and PPE in order to introduce products to help with COVID-19 relief efforts.

While entering a highly regulated space may seem daunting, we are able to help companies navigate all aspects of the medical device life cycle seamlessly and successfully.

Use the guide below in helping you make an initial assessment of the considerations for diversifying your business operations, expanding your market opportunities, and entering the COVID-19 marketplace. Contact a member of the Morgan Lewis life sciences team for further guidance after you have completed your initial assessment.



IDENTIFY A PRODUCT

- ☐ Do I make a simple product (face mask, glove) or a more complex product (thermal camera or patient screening software)?
- ☐ Can I take one of my existing nonmedical products/technologies and use it for a medical purpose (e.g., air purifier, thermal imaging camera)?
- ☐ Do I have sufficient in-house engineering and manufacturing capabilities and capacity to support the product?
- ☐ Should I license (do I need to license) technology from another company?
- ☐ How do I protect the intellectual property of my product?
- ☐ Are there business cooperation opportunities available that will allow me to leverage my products/production?

EVALUATE THE REGULATORY PATHWAY TO MARKET

- ☐ Does the product require government review/approval before entering the marketplace?
- ☐ Has the government issued Discretionary Enforcement Policies/Guidance Documents that ease the regulatory burden?
- ☐ Do I want to only produce the product during the period of the pandemic or do I see long-term value with the product?
- ☐ Do I need to register and/or list my product with a government agency (e.g., the FDA)?
- ☐ Are there any local/state requirements that I need to know?
- ☐ Do I plan on exporting my products to foreign jurisdictions?

ESTABLISH MANUFACTURING OPERATIONS

- ☐ Do I have a quality system (does it meet any relevant standards, i.e., ISO 9001, ISO 13485, 21 C.F.R. 820)?
- ☐ Do I need to make any changes to my existing procedures and policies?
- ☐ What equipment do I need to purchase or convert in order to manufacture the product?
- ☐ Do I have enough component and material suppliers to manufacture my product?
- ☐ Do I need to amend existing agreements or enter into new quality agreements with my existing suppliers that will produce components for my product?

RESOURCE CHECK

- ☐ Do I need to hire additional support staff?
- ☐ Should I hire consultants to perform certain quality and regulatory functions?
- ☐ Do I need to install additional systems to manage my production and ensure regulatory compliance?
- ☐ Have I evaluated the relevant laws and regulations for worker safety?
- ☐ Do I have the necessary insurance in place to allow me to operate in the medical device sector?

MARKET THE PRODUCT

- ☐ Create product labeling, educational and promotional materials that are consistent with the regulatory pathway and laws governing marketing of medical devices.
- ☐ Do I intend on selling my products to government entities, including hospitals/health systems that may be operated by or healthcare providers who may be employed by national governments?
- ☐ Do I plan on marketing directly to consumers?
- ☐ Do I plan on marketing directly to healthcare providers?
- ☐ Do I intend to use healthcare providers as consultants to develop or market my product or otherwise interact with healthcare providers? If so, do I need to create procedures and policies to govern those interactions?
- ☐ Do I have systems in place that I can convert to capture data necessary to comply with transparency reporting obligations applicable to medical device manufacturers?
- ☐ Am I protecting patient privacy and health information?
- ☐ Can I seek reimbursement of my product from a government program (i.e., Medicare/Medicaid, foreign health authority)?

MONITOR THE PRODUCT'S PERFORMANCE

- ☐ Have I established processes to receive feedback from my customers?
- ☐ Do I have the ability (both personnel and systems) to promptly report adverse events to regulatory authorities?
- ☐ Do I have policies and procedures in place that allow for responding to post-market feedback to improve my product?

MORGAN LEWIS LIFE SCIENCES TEAM

Morgan Lewis has experience in supporting all aspects of the life cycle of a medical device marketed and sold around the world, including lawyers that focus on the following:

- **FDA Medical Device Regulatory Counseling**
- **European Union and Asian Medical Device Regulatory Counseling**
- **Life Science Transactions and Agreements**
- **Healthcare (including HIPAA, data protection, interacting with healthcare providers, and reimbursement)**
- **Labor and Employment/ Workplace Issues**
- **Intellectual Property**

To get started on your COVID-19 project, contact a member of our life sciences team:

Dennis Gucciardo
Partner | Washington, DC
dennis.gucciardo@morganlewis.com
+1.202.739.5278

Paul Ranson
Consultant | London
paul.ranson@morganlewis.com
+44.20.3201.5660

David Glazer
Partner | Princeton
david.glazer@morganlewis.com
+1.609.919.6624

Todd Liao
International Partner | Shanghai
todd.liao@morganlewis.com
+86.21.8022.8799

Joachim Heine
Partner | Frankfurt
joachim.heine@morganlewis.com
+49.69.7140.0759

Scott Memmott
Partner | Washington, DC
scott.memmott@morganlewis.com
+1.202.739.5098

Sharon P. Masling
Partner | Washington, DC
sharon.masling@morganlewis.com
+1.202.739.5299

Krista Vink Venegas
Partner | Chicago
krista.venegas@morganlewis.com
+1.312.324.1736

Morgan Lewis

Connect with us 

www.morganlewis.com

© 2020 Morgan, Lewis & Bockius LLP

© 2020 Morgan Lewis Stamford LLC

© 2020 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

*Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners. Morgan Lewis Stamford LLC is a Singapore law corporation affiliated with Morgan, Lewis & Bockius LLP.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.

081220_ 201602_LTR