Disclaimers

The information provided above is general reimbursement information for LUMASON. It is not legal advice, nor is it advice about how to code, complete or submit any particular claim for payment. Although we supply this information based on our current knowledge, it is always the provider’s responsibility to determine and submit appropriate codes, charges, modifiers and bills for the services that were rendered. This coding and reimbursement information is subject to change without notice. Payers or their local branches may have their own coding and reimbursement requirements and policies. Before filing any claims, providers should verify current requirements and policies with the payer.

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CPT is a registered trademark of the American Medical Association.
INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:
• in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
• in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

CONTRAINDICATIONS
LUMASON is contraindicated in patients with:
• Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts
• History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

Please see full Prescribing Information including boxed WARNING at http://imaging.bracco.com/us-en/lumason.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by BRACCO Suisse S.A., Plan-les-Ouates Geneve, Switzerland (Lumason lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride, 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

LUMASON is a registered trademark of Bracco Diagnostics Inc.
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Bracco Diagnostics Inc. Reimbursement Hotline:
1-800-349-1388
askbracco@reimbursement.bracco.com
INDICATIONS AND USAGE

LUMASON is an ultrasound contrast agent indicated for use:

- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

LUMASON is the first and only ultrasound contrast agent approved by the U.S. Food and Drug Administration for use in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients.

CONTRAINDICATIONS

LUMASON is contraindicated in patients with:

- Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts
- History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

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II. LUMASON® REIMBURSEMENT OVERVIEW

Reimbursement is a function of 3 key components: Coding, Coverage, and Payment. Each component needs to be in place and meet the requirements in order to receive reimbursement.

1. Coding

There is pass-through coding in place for LUMASON. HCPCS code: Q9950 effective January 1, 2016.

Underlying payment and coverage decisions for medical technology is the process of coding. Codes are composed of systematic numbers and descriptors which identify procedures and products. Developed through the efforts of such organizations as the American Medical Association (AMA), the American Hospital Association (AHA), and the Centers for Medicare and Medicaid Services (CMS), codes can be important for technology manufacturers and providers because they enable an insurer to recognize and process claims involving the use of a product. Thus, a code can contribute to product coverage and payment.

2. Coverage

Coverage refers to the process and criteria used to determine whether a product, service, or procedure will be reimbursed. The most powerful and influential entity in the coverage process is Medicare. Medicare’s coverage policies influence the private-sector insurance market where private payers follow Medicare’s lead in applying cost control policies. In many cases, if Medicare does not cover a new technology, the likelihood of it being covered by other payers is remote.

3. Payment

Once products are covered, they are eligible for payment. This introduces a new set of methodologies to determine the exact payment amount, as well as a new set of incentives that influence the use and development of medical technologies. These payment methods depend on where the technology is used, by whom, and the kind of treatment service that is provided.

LUMASON has Transitional Pass-Through Payment Status until December 31, 2017 with code Q9950.
INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:
• in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
• in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

CONTRAINDICATIONS
LUMASON is contraindicated in patients with:
• Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts
• History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

IMPORTANT SAFETY INFORMATION:
WARNING: SERIOUS CARDIOPULMONARY REACTIONS
Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].
• Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
• Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

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II. LUMASON® IN ECHOCARDIOGRAPHY

A. MEDICARE CODING AND PAYMENT OVERVIEW

Table 1: Medicare Coding and Payment Overview – Contrast National Average Reimbursement Rates

<table>
<thead>
<tr>
<th>Procedure Setting</th>
<th>Reimbursement</th>
<th>Code</th>
<th>2016 Reimbursement Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOPPS (Hospital Outpatient Setting)</td>
<td>Medicare packages payment for contrast imaging agents into the payment for the associated procedure(^2)</td>
<td>C8929(^3)</td>
<td>$670.96(^3)</td>
</tr>
<tr>
<td></td>
<td>Other HCPCS codes exist depending on the type of study completed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOPPS Transitional Pass-Through Code for LUMASON only</td>
<td>Temporary additional HOPPS payment for innovative medical devices, drugs and biologicals for Medicare beneficiaries.(^4) It is not subject to coinsurance or packaging rules.</td>
<td>Q9950(^5)</td>
<td>Updated quarterly based on Average Sales Price (ASP) + 6%(^5,6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Five mL per vial(^1)</td>
</tr>
<tr>
<td>Hospital In-patient</td>
<td>Part of MS-DRG payment(^7)</td>
<td>ICD-10-PCS(^8)</td>
<td>No separate reimbursement for contrast agents(^7)</td>
</tr>
<tr>
<td>Physician Office and Free Standing Imaging Centers</td>
<td>Medicare Physician Fee Schedule(^9)</td>
<td>CPT(^®) 93303, 93304, 93306 93307, 93308(^11) &amp; Q9950(^5)</td>
<td>See Medicare Physician Fee Schedule(^9)</td>
</tr>
<tr>
<td></td>
<td>&amp; Medicare Part B payment(^10)</td>
<td></td>
<td>Updated quarterly based on ASP + 6%(^12)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Final payment determined by individual carriers</td>
</tr>
</tbody>
</table>

\(^{1}\) https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html
\(^{2}\) ASP: Average Selling Price

B. USE OF LUMASON IN THE OUTPATIENT HOSPITAL SETTING (HOPPS)

Payment in an outpatient hospital is based on a prospective payment system. The system is based on groups of procedures, medical visits, and ancillary services.\(^4\)

Under the HOPPS system, contrast agents are not separately payable; rather they are packaged into the Ambulatory Payment Categories (APC) for the procedure with which they are utilized.\(^2\)
**INDICATIONS AND USAGE**

**LUMASON** is an ultrasound contrast agent indicated for use:
- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms.
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients.

**CONTRAINDICATIONS**

**LUMASON** is contraindicated in patients with:
- Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts.
- History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON.

*IMPORTANT SAFETY INFORMATION:*

**WARNING: SERIOUS CARDIOPULMONARY REACTIONS**

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].
- Assess all patients for the presence of any condition that precludes administration [see Contraindications (4)].
- Always have resuscitation equipment and trained personnel readily available [see Warnings and Precautions (5.1)].

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

Please see full Prescribing Information including boxed WARNING at http://imaging.bracco.com/us-en/lumason.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

**Table 2: 2016 APC 5561 and 5562 Rates (National Average Medicare Rates for Echocardiography)**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Payment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>C8921</td>
<td>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete</td>
<td>$670.96</td>
</tr>
<tr>
<td>C8922</td>
<td>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study</td>
<td>$454.05</td>
</tr>
<tr>
<td>C8923</td>
<td>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography</td>
<td>$454.05</td>
</tr>
<tr>
<td>C8924</td>
<td>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording when performed, follow-up or limited study</td>
<td>$454.05</td>
</tr>
<tr>
<td>C8929</td>
<td>Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), included m-mode recording, when performed, completed, with spectral doppler echocardiography, and with color flow doppler echocardiography</td>
<td>$670.96</td>
</tr>
</tbody>
</table>
C. TRANSITIONAL PASS-THROUGH CODE SUMMARY

The Centers for Medicare and Medicaid Services (CMS), under the Social Security Act (the Act), provides for temporary additional payments or “transitional pass-through payments” for certain innovative medical devices, drugs, and biologicals for Medicare beneficiaries.4

Section 1833(t)(6)(B) of the Act, requires that, under the HOPPS, categories of devices will be eligible for transitional pass-through payments for at least two, but not more than three years. Section 1833(t)(6)(B)(ii)(IV) of the Act, requires that CMS will create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.13

New for January 1, 2016

As of January 1, 2016, one would report Q9950 when using the LUMASON contrast agent in conjunction with the appropriate ultrasound procedure. LUMASON’s pass-through payment is updated quarterly based on average sales price + 6%5,6 and will be effective until Dec. 31, 2017. There are five mL in a single LUMASON vial1, and LUMASON is billed per mL.

D. IMAGING WITH LUMASON IN THE INPATIENT HOSPITAL SETTING

Inpatient Coding

ICD-10-PCS procedure codes, which are used only for inpatient billing, indicate the surgical and/or diagnostic procedures performed on the patient. These codes in combination with diagnosis codes may help to determine assignment to a MS-DRG (payment category) under Medicare and other payment systems.8

Inpatient Payment

Payment for inpatient hospital services is based on a classification system determined by patient diagnosis known as Medicare Severity Adjusted Diagnosis Related Groups or MS-DRGs. Under MS-DRGs, a hospital is paid at a predetermined, specific rate for each Medicare discharge. Fixed prices are established for hospital services based on the patient diagnosis and are paid regardless of the actual cost the hospital incurs in providing these services.7 The ultrasound exam and contrast agent are part of the MS-DRG payment.
E. LUMASON IN THE PHYSICIAN OFFICE/IDTF SETTING

When performed in the physicians’ office or IDTF, Q9950 Injection, sulfur hexafluoride lipid microsphere, would be reported along with the appropriate 933xx CPT® code¹¹ for the echocardiography procedure. Q9950 indicates the use of LUMASON contrast agent.⁵ Payment amounts are based upon manufacturer reported Average Sales Price (ASP) + 6% which is reimbursed at the discretion of the Local Medicare Contractors.¹²

For Medicare Part B Payment, you can visit:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html

For Medicare physician fee schedule, you can visit:


It is recommended that you check with your individual payer for their specific coding, coverage, preauthorization, and payment requirements.

INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:
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• in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

CONTRAINDICATIONS
LUMASON is contraindicated in patients with:
• Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts
• History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

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III. LUMASON IN ULTRASONOGRAPHY OF THE LIVER

A. MEDICARE CODING AND PAYMENT OVERVIEW

Table 3: Medicare Coding and Payment Overview – Contrast National Average Reimbursement Rates

<table>
<thead>
<tr>
<th>Procedure Setting</th>
<th>Reimbursement</th>
<th>Code</th>
<th>2016 Reimbursement Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOPPS (Hospital Outpatient Setting)</td>
<td>Medicare packages payment for contrast imaging agents into the payment for the associated procedure²</td>
<td>CPT® 76700 Ultrasound, abdominal, w/real-time documentation, complete¹⁴ or CPT® 76705 Ultrasound, abdominal, w/real-time documentation, limited¹⁴</td>
<td>$153.58⁶</td>
</tr>
<tr>
<td>HOPPS Transitional Pass-Through Code for LUMASON only</td>
<td>Temporary additional HOPPS payment for innovative medical devices, drugs and biologicals for Medicare beneficiaries.⁴ It is not subject to coinsurance or packaging rules.</td>
<td>Q9950⁵</td>
<td>Updated quarterly based on Average Sales Price (ASP) + 6%⁵,⁶ Five mL per vial¹</td>
</tr>
<tr>
<td>Hospital In-patient</td>
<td>Part of MS-DRG payment⁷</td>
<td>ICD-10-PCS⁸</td>
<td>No separate reimbursement for contrast agents⁷</td>
</tr>
<tr>
<td>Physician Office and Free Standing Imaging Centers</td>
<td>Medicare Physician Fee Schedule⁹ &amp; Medicare Part B payment¹⁰</td>
<td>CPT® 76700 Ultrasound, abdominal, w/real-time documentation, complete¹⁴ or CPT® 76705 Ultrasound, abdominal, w/real-time documentation, limited¹⁴ &amp; Q9950⁵</td>
<td>$124.24⁹ $92.73³</td>
</tr>
</tbody>
</table>
INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:
• in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
• in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

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B. USE OF LUMASON IN THE OUTPATIENT HOSPITAL SETTING (HOPPS)

Payment in an outpatient hospital is based on a prospective payment system. The system is based on groups of procedures, medical visits, and ancillary services.4

Under the HOPPS system, contrast agents are not separately payable; rather they are packaged into the Ambulatory Payment Categories (APC) for the procedure with which they are utilized.2
### Table 4: 2016 APC 5532 Rate (National Average Medicare Rates)\(^3\)

<table>
<thead>
<tr>
<th>APC/ CPT Codes</th>
<th>Description</th>
<th>Payment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contrast Procedures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76700(^{14})</td>
<td>Ultrasound, abdominal, w/real-time documentation, complete</td>
<td>$153.58(^5)</td>
</tr>
<tr>
<td>76705(^{14})</td>
<td>Ultrasound, abdominal, w/real-time documentation, limited</td>
<td>$153.58(^5)</td>
</tr>
<tr>
<td></td>
<td>(e.g. single organ, quadrant)</td>
<td></td>
</tr>
<tr>
<td>Q9950(^6)</td>
<td>HOPPS transitional Pass-Through Payment is for LUMASON only. It is not subject to coinsurance or packaging rules.</td>
<td>Updated quarterly based on ASP + 6(^{5,6})</td>
</tr>
</tbody>
</table>

### C. TRANSITIONAL PASS-THROUGH CODE SUMMARY

The Centers for Medicare and Medicaid Services (CMS), under the Social Security Act (the Act), provides for temporary additional payments or “transitional pass-through payments” for certain innovative medical devices, drugs, and biologicals for Medicare beneficiaries.\(^4\)

Section 1833(t)(6)(B) of the Act, requires that, under the HOPPS, categories of devices will be eligible for transitional pass-through payments for at least two, but not more than three years. Section 1833(t)(6)(B)(i)(IV) of the Act, requires that CMS will create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.\(^{13}\)

**New for January 1, 2016**

As of January 1, 2016, one would report Q9950 when using the LUMASON contrast agent in conjunction with the appropriate ultrasound procedure. LUMASON’s pass-through payment is updated quarterly based on average sales price + 6\(^{5,6}\) and will be effective until Dec. 31, 2017. There are five mL in a single LUMASON vial\(^1\), and LUMASON is billed per mL.
D. IMAGING WITH LUMASON IN THE INPATIENT HOSPITAL SETTING

Inpatient Coding

ICD-10-PCS procedure codes, which are used only for inpatient billing, indicate the surgical and/or diagnostic procedures performed on the patient. These codes in combination with diagnosis codes may help to determine assignment to a MS-DRG (payment category) under Medicare and other payment systems.8

Inpatient Payment

Payment for inpatient hospital services is based on a classification system determined by patient diagnosis known as Medicare Severity Adjusted Diagnosis Related Groups or MS-DRGs. Under MS-DRGs, a hospital is paid at a predetermined, specific rate for each Medicare discharge. Fixed prices are established for hospital services based on the patient diagnosis and are paid regardless of the actual cost the hospital incurs in providing these services.7 The ultrasound exam and contrast agent are part of the MS-DRG payment.
E. LUMASON IN THE PHYSICIAN OFFICE/IDTF SETTING

When performed in the physician’s office or IDTF, Q9950 Injection, sulfur hexafluoride lipid microsphere, is reported along with the appropriate CPT® code: 76700 for Ultrasound, abdominal, w/ real time documentation, complete or, 76705 for Ultrasound, abdominal, w/real time documentation, limited. Q9950 indicates the use of LUMASON contrast agent. Payment amounts are based upon manufacturer reported Average Sales Price (ASP) + 6% which is reimbursed at the discretion of the Local Medicare Contractors.

For Medicare Part B Payment, you can visit:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html

For Medicare physician fee schedule, you can visit:


It is recommended that you check with your individual payer for their specific coding, coverage, preauthorization, and payment requirements.

Please refer to the Prescribing Information, including boxed WARNING, inside the pocket of this brochure for complete dosing instructions and additional product information.

References:
References Accessed May 2016
3 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending
5 https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpp/Addendum-A-and-Addendum-B-Updates.html
9 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FFSlookup/index.html
12 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html
INDICATIONS AND USAGE
LUMASON is an ultrasound contrast agent indicated for use:

• in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms

• in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients

CONTRAINDICATIONS
LUMASON is contraindicated in patients with:

• Known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts

• History of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

The risk for serious cardiopulmonary reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias) [see Warnings and Precautions (5.1)].

Please see full Prescribing Information including boxed WARNING at http://imaging.bracco.com/us-en/lumason.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by BRACCO Suisse S.A., Plan-les-Ouates Geneve, Switzerland (LUMASON lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride, 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

LUMASON is a registered trademark of Bracco Diagnostics Inc.